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Guidance for the Reregistration of Pesticide Products Containing Phorate as the Active Ingredient

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Guidance for the Reregistration of Pesticide Products Containing PHORATE as the Active Ingredient

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REGISTRATION STANDARD
(SECOND ROUND REVIEW)

FOR THE

REREGISTRATION OF PESTICIDE PRODUCTS

CONTAINING

PHORATE

AS THE ACTIVE INGREDIENT

CAS REGISTRY NO. 298-02-2

OPP Chemical Code 057201

EPA CASE NUMBER 103

December, 1988

ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF PESTICIDE PROGRAMS
WASHINGTON, D.C. 20460

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EPA Form 8580-3	Generic Data Exemption Statement

GLOSSARY OF TERMS AND ABBREVIATIONS

ADI	Acceptable Daily Intake. Also known as the Reference Dose or RfD.
a.i.	active ingredient.
ARC	Anticipated Residue Contribution
CAS	Chemical Abstracts Service
CSF	Confidential Statement of Formula
EEC	Estimated Environmental Concentration. The estimated pesticide concentration in an environment, such as a terrestrial ecosystem.
EP	End Use Product
EPA	U.S. Environmental Protection Agency
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FFDCA	Federal Food, Drug, and Cosmetic Act
LC_{50}	Median lethal concentration - a statistically derived concentration of a substance that can be expected to cause death in 50% of test animals. It is usually expressed as the weight of substance per weight or volume of water or feed, e.g., mg/l or ppm.
LD_{50}	Median lethal dose - a statistically derived single dose than can be expected to cause death in 50% of the test animals, when administered by the route indicated (oral, dermal, inhalation). It is expressed as a weight of substance per unit weight of animal, e.g., mg/kg.
LEL	Lowest Effect Level
MPI	Maximum Permissible Intake
MRID	Master Record Identification (number). EPA's system of recording and tracking studies submitted to the Agency.
MP	Manufacturing Use Product
NPDES	National Pollutant Discharge Elimination System
NOEL	No Observed Effect Level

OPP	Office of Pesticide Programs
PADI	Provisional Acceptable Daily Intake
ppm	parts per million
RfD	Reference Dose
TMRC	Theoretical Maximal Residue Contribution

I. INTRODUCTION

This document is a revised Registration Standard for the subject chemical. In its original Standard, issued in August, 1984, the Agency summarized the available data supporting the registration of the pesticide and its assessment of those data to determine whether the pesticide met the "no unreasonable adverse effects" standard of FIFRA. The Agency concluded that additional data were necessary to fully evaluate the pesticide, and, as part of the issuance of the Standard, required that registrants supply those data. The Standard also set out labeling requirements that the Agency believed were necessary to ensure that products containing the pesticide were adequate to protect public health and the environment while the data were under development.

The Agency has since reviewed the additional data and has updated and revised its scientific and regulatory conclusions concerning the pesticide in light of expanded data requirements promulgated in 1984 as 40 CFR Part 158. The Registration Standard contains the Agency's updated scientific assessment[1] of this pesticide and its currently registered uses. As part of its review, the Agency has reassessed the tolerances for the pesticide and determined whether they are adequate. The tolerance reassessment is included in this Registration Standard.

Based on the new data, the Agency has also reviewed the labeling requirements for the pesticide and is requiring label revisions.

This revised Registration Standard supersedes the original Registration Standard in its entirety.

This document contains the following sections:

- Section II describes the particular pesticide(s) covered by this Registration Standard, and gives a brief profile of its usage and composition. Regulatory history may be provided as well.
- Section III sets out the Agency's scientific assessment of the health risks and environmental characteristics and effects of the chemical, updated

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[1] As of April 1, 1988 the scientific reviews and Compendium of Acceptable Uses may be obtained from the National Technical Information Services (NTIS), Attn: Order Desk, 5385 Port Royal Road, Springfield, VA 22161 (tel:703:487-4650).

based on data submitted to the Agency under the original Registration Standard.

- Section IV explains the regulatory decisions and conclusions arising from the Agency's assessment, and the rationales for its decisions. Section V describes the labeling statements required for products containing the chemical. These are divided into statements for manufacturing use products and statements for end use products.

- Sections VI, VII, VIII, IX and X describe what products are subject to the data and labeling requirements set out in this Registration Standard, and what is required of registrants to comply with the requirements.

- Appendix I contains a series of tables setting out data requirements for the chemical. The tables identify which requirements have been satisfied, as well as those for which gaps remain. A Guide to Tables introduces the tables.

- Appendix II is a series of labeling information sheets, setting out general labeling information that must be placed on labeling.

- Appendix III is a bibliography of the data evaluated by the Agency in its assessment. A Guide to Bibliography explains how to read and use the Bibliography.

- Appendix IV contains the necessary forms to respond to receipt of the Standard

Registrants are reminded that FIFRA sec. 6(a)(2) requires them to submit factual information concerning possible unreasonable adverse effects of a pesticide at any time that they become aware of such information. Registrants must notify the Agency of any information, including interim or preliminary results of studies, if that information suggests possible adverse effects on man or the environment. This requirement is independent of the specific time requirements imposed by EPA for submission of completed studies called in by the Agency and continues as long as the products are registered under FIFRA.

II. CHEMICAL COVERED BY THIS STANDARD

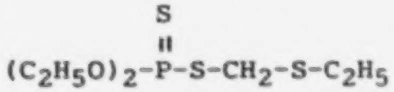
A. DESCRIPTION OF CHEMICAL

The following chemical is covered by this Registration Standard:

Common Name: Phorate

Generic (Chemical) Name: O,O-diethyl S-[(ethylthio)methyl] phosphorodithioate

Chemical Structure:



$$(C_2H_5O)_2-\overset{\overset{S}{\|}}{P}-S-CH_2-S-C_2H_5$$

Chemical Family: Systemic organophosphate

Trade Names: Thimet, AAstar and Rampart

Other Chemical Nomenclature: O,O-diethyl S-[(ethylthio)methyl] ester and O,O-diethyl-S-(ethylthio) methyl phosphorodithioate

CAS Registry Number: 298-02-2

EPA Pesticide Chemical Code (Shaughnessy Number): 057201

Empirical Formula: $C_7H_{17}O_2PS_3$

Molecular Weight: 260.4

Chemical/Physical Characteristics:

Color: pale straw to light brown (TGAI, 2749-106); colorless to very light yellow (TGAI, 241-212 and 241-213)

Physical state: liquid (TGAI, 2749-106, 241-212 and 241-213)

Odor: characteristic of mercaptan containing compounds (TGAI, 241-212 and 241-213)

Boiling Point: 118-120 C, 0.8 mm Hg (TGAI, 2749-106)

Specific Gravity: 1.15 at 20 C (TGAI, 2749-106); 1.17 at 25 C (TGAI for 241-212 and 241-213)

Solubility: 50 mg/l in water; miscible with carbon tetrachloride, vegetable oils (unspecified), xylene, and unspecified alcohols, ethers and esters (TGAI, 2749-106)

pH: 5-7 (TGAI, 2749-106); 3.56-3.81 (TGAI, 241-212 and 241-213)

Viscosity: 80 cps at 21 C (TGAI, 241-212 and 241-213)

Corrosion: non-corrosive to steel, aluminum, porcelain, fiberglass, and phenolic resins (TGAI, 241-212 and 241-213)

B. USE PROFILE

Type of Pesticide: Insecticide and Nematicide

Year of Initial Registration: 1959

Registered Uses: Terrestrial food crop use on beans, barley, corn, cotton, hops, peanuts, potatoes, sorghum, soybeans, sugar beets, sugarcane, and wheat.

Terrestrial non-food crop use on lilies (bulb production).

Pests Controlled: Various leaf-feeding insects, mites, and soil insects

Methods of application: Soil and foliar applications (band, broadcast, in-furrow and drilling) using conventional ground and aerial equipment

Annual Usage: 4.56 million pounds active ingredient (1987 estimate)

Predominant Usage: Predominant use is on field corn, comprising approximately 70% of annual usage followed by 10% on potatoes, and less than 5% individually on other crops

Mode of Activity: Toxic action is exerted by inhibiting enzymes of the nervous system (cholinesteras inhibition)

Formulations: Granular (0.2%, 0.4%, 6.5%, 10%, 15%, and 20%)

U.S. Registrants: American Cyanamid Company, Uniroyal Chemical Company Inc., Aceto Chemical Company Inc., Wilbur Ellis Co., Riverside Terra Corp., Farm Bureau Cooperative, and Platte Chemical Co.

Number of Registrations: 14 federally registered end-use products, 2 technical products, 1 formulation intermediate, and 19 "special local need" registrations issued under FIFRA section 24(c).

III. AGENCY FINDINGS

A. SUMMARY

The Agency has reviewed all data currently supporting the registration of phorate. Based on the available data, EPA has reached the following conclusions. The points summarized below are presented in further detail, in the context of EPA's science findings and additional data requirements, in Sections B through D.

1. The results of acceptable acute toxicity studies show that technical phorate is in Toxicity Category I by the oral, dermal and inhalation routes. Acute intoxication from phorate is evident from typical cholinergic signs. The acute oral administration of phorate to hens did not cause a delayed neurotoxic effect.

2. Based on results of acceptable subchronic and chronic feeding studies with rats and dogs, cholinesterase (plasma, blood or brain) is the primary target for phorate. The occasional suppression of body weight and/or food consumption observed in these studies are viewed as secondary effects. Based on the NOEL for brain cholinesterase inhibition in a one year dog study (NOEL = 0.05 mg/kg) and applying an uncertainty factor of 100, the RfD was determined to be 0.0005 mg/kg/day.

3. Based on the results of acceptable teratology and reproduction studies, phorate does not induce teratogenic effects. Slight fetotoxic effects in a 3-generation reproduction study in mice and fetotoxic and maternal toxicity in a teratology study in rats were the only changes indicative of developmental toxicity. The NOEL for developmental toxicity, 0.23 mg/kg, is based on the fetotoxic effects observed in the 3-generation mouse study, the lowest NOEL observed.

4. Phorate does not produce oncogenic effects, based on results of acceptable chronic studies in which ingestion of phorate did not induce an oncogenic response in rats or dogs. Based on a reevaluation of the mouse study, the evidence does not show that a Maximum Tolerated Dose (MTD) was attained. Confirmatory data are required.

5. Phorate did not cause a mutagenic response in several in vitro (microbial and mammalian cells) studies or in an in vivo dominant lethal study.

6. Results of an acceptable metabolism study using male rats indicated that a large proportion of phorate labeled metabolites were excreted in urine and feces within

24 hours of dosing, while the levels of radioactivity in tissues were low. Most of the total radioactivity measured in urine, kidney, muscle (leg) and liver was composed of a non-phosphorylated series of phorate metabolites. The oxidative, phosphorylated products (metabolites of phorate which are more potent anticholinesterase compounds through oxidative desulfuration and/or sulfide oxidation) represented a minor proportion of the phorate metabolites measured. A comparable metabolism study using female rats is required to fulfill Agency Guideline requirements.

7. The Agency is requiring special acute and subchronic studies to determine if phorate has a systemic effect on the eye. Phorate is structurally related to other organophosphate compounds which have been implicated in causing human eye effects, such as retinal degeneration and myopia.

8. Based on recently submitted data, phorate does not appear to be a potential leacher. However, its sulfone and sulfoxide degradates show greater persistence and mobility in soil, and therefore may have a greater leaching potential. Due to inadequate information on aerobic/anaerobic soil metabolism and field dissipation of phorate and its degradates, the requirement for groundwater monitoring studies is deferred at this time. However, a terrestrial field dissipation study is required to be conducted on sandy loam soil in Long Island, New York. All samples must be analyzed for phorate, sulfoxide, and sulfone degradates.

9. Based on acceptable laboratory data, technical phorate is characterized as very highly toxic to birds on an acute oral basis and highly toxic to birds on a subacute dietary basis. Phorate is characterized as very highly toxic to mammals on a subacute dietary basis.

10. Based on acceptable laboratory data, phorate is characterized as very highly toxic to freshwater fish and aquatic invertebrates and estuarine and marine organisms. Based on phorate's high toxicity to aquatic organisms and reported fish kills, an aquatic field study was required in the 1984 Standard. This study is currently in progress and is due in 1991. A full assessment of this hazard potential will be made upon receipt of these data.

11. Many of the tolerances for phorate are still not adequately supported. Additional data (residue studies, residue analytical methods, processing and cooking studies, poultry metabolism study and storage stability data) are needed before the Agency can determine the adequacy of current tolerance levels and perform a tolerance reassessment.

12. Based on data submitted in response to the 1984 Standard, the Agency has calculated the Anticipated Residue Contribution (ARC) for the U.S. population average to be 0.000491 mg/kg/day, corresponding to 98% of the RfD. The ARC assumes residues are present at tolerance levels, but takes into account percent of crop treated, where possible. For children 1 to 6 years of age, the ARC occupies 235% of the RfD, and for non-nursing infants, the ARC occupies 331% of the RfD.

B. HEALTH EFFECTS ASSESSMENT

Below is an assessment of the human health risks associated with the insecticide phorate based upon data submitted in response to the 1984 Phorate Registration Standard, and data previously reviewed and determined to be acceptable to support registration of products containing phorate.

1. Acute Toxicity

There are adequate acute toxicity studies available for phorate. Technical phorate is highly toxic on an acute oral, dermal, and inhalation basis. It falls in Toxicity I by the oral route of exposure based acute LD_{50} values of 3.7 and 1.4 mg/kg in male and female rats, respectively. All of the animals that died in this study exhibited typical signs of cholinergic intoxication such as salivation, lacrimation, exophthalmos, muscle fasciculation, excessive urination and defecation. Technical phorate is in Toxicity Category I for dermal exposure based on LD_{50} values of 9.3 and 3.9 mg/kg in male and female rats, respectively. The cholinergic signs noted for the acute oral study were also observed in the acute dermal study. Based on a 1-hour exposure to analytical grade phorate aerosol, the LC_{50}s for rat were 60 and 11 mg/m3 for males and females, respectively (Toxicity Category I). Typical cholinergic signs were observed in intoxicated animals. No data are available on the primary eye or primary dermal irritation properties of phorate. However, these tests are not required since the toxicity of phorate prohibits the administration of appropriate dosage levels. Likewise, no data are available on the primary dermal sensitization properties of phorate, but this study is not required because of the high acute toxicity of phorate.

There is an acceptable acute delayed neurotoxicity study on file to support registration of products containing phorate. The oral administration of technical phorate in corn oil to 50 randomly selected hens at a dosage level of 14.2 mg/kg (oral LD_{50} of phorate in white leghorn hens), followed by a 21-day interval and a second administration at the same dosage level, did not cause neurological changes indicative of a delayed neurotoxic response.

2. Subchronic Toxicity

The Agency does not have an acceptable subchronic non-rodent (dog) study to support registration of products containing phorate. However, the Agency is not making this a requirement, since acceptable chronic data for the non-rodent are available. There is a subchronic rodent (rat) study, which is flawed in that histopathology was performed on 3 (not 10) rats/sex in the control and 3 test groups (2.0, 6.0 and 12.0 ppm). However, a new subchronic rodent (rat) study is not required, since the target endpoint (cholinesterase) inhibition was satisfactorily identified in this rat study, and also because results of acceptable subchronic data in which rodents were administered phorate sulfoxide (a toxic metabolite of phorate) are consistent with those established in a non-rodent study. In this rat subchronic rat study, technical phorate was administered in the diet to rats for 90 days at dosage levels of 0.22, 0.66, 2.0, 6.0 12.0 and 18.0 ppm. The 12.0 and 18.0 ppm dosage groups each consisted of 25 rats/sex, each of the remaining groups had 50 rats/sex. Body weight gain and food consumption were suppressed and mortalities were induced at the 12.0 and 18.0 ppm levels. Erythrocyte cholinesterase (ChE) activity was inhibited in females at 2.0 ppm while plasma, red blood cell (RBC) and brain ChE activity was inhibited in both sexes at the 6.0 ppm level of phorate. Treatment-related histopathologic changes were not noted. The LEL in this study was 2.0 ppm(0.1 mg/kg/day) while the NOEL was 0.66 ppm (0.033 mg/kg/day).

No data are available on the 21-day subchronic dermal toxicity of phorate. This study is not required since the highly toxic nature of phorate prohibits the administration of dosages that could induce an adverse effect other than inhibition of cholinesterase activity. No data are available on the subchronic neurotoxicity of phorate. Since there was no evidence of delayed neurotoxicity in an acute study in hens, data from a subchronic neurotoxicity study are not required.

3. Chronic Toxicity/Oncogenicity Testing

Chronic toxicity/ oncogenicity studies are discussed below.

Dog Study

Sufficient chronic toxicity data are available from a non-rodent (dog) study. In this study, technical phorate was administered orally in capsules to dogs (6/sex/group) for 1 year at daily dosage levels of 5, 10, 50 and 250 ug/kg. Compound-related effects included slight body tremors in high-dose males and females and marginal inhibition of body weight gain in high-dose males. Plasma cholinesterase was inhibited at 50 ug/kg/day in both sexes. Red blood cell (RBC) and brain cholinesterase were inhibited in both sexes at 250 ug/kg/day. The NOEL and LEL for systemic toxicity were 50 and 250 ug/kg/day, respectively. The LELs for cholinesterase inhibition were: plasma-50 ug/kg/day; RBC and brain-250 ug/kg/day. The corresponding NOELs were: plasma-10 ug/kg/day; RBC and brain-50 ug/kg/day.

Rat Study

The available rodent chronic feeding study using technical phorate only partially satisfies the requirement for chronic toxicity testing in that although the target endpoint (inhibited cholinesterase activity) was identified, the study did not achieve an NOEL. However, this study does not have to be repeated, since a NOEL and LEL, based on the same endpoint, were adequately achieved in a subchronic feeding study in rats (see discussion above under Subchronic Toxicity).

In this study, rats (50/sex/group) received technical phorate in the diet at levels of 1 (0.05 mg/kg), 3 (0.15 mg/kg) and 6 (0.30 mg.kg) ppm for a period of 2 years. Plasma ChE activity was inhibited in low-dose (1 ppm) males at 24 months and in mid-dose (3 ppm) males at 24 months and females at 6, 12 and 24 months. Brain ChE activity was also inhibited in females at this dosage level. Plasma ChE was inhibited in high-dose (6 ppm) males at 12 and 24 months and high-dose females at 3,6, 12 and 24 months. Brain and RBC (measured only at termination) ChE activity were each inhibited in both sexes at the high dosage level. Survival as well as body weight gain and food consumption were suppressed in high-dose females. There was a possible relationship between treatment and forestomach irritation in high-dose males and females. The LEL, based on plasma ChE inhibition in males, was 1 ppm (0.05 mg/kg/day); the NOEL was not determined. The chronic toxicity portion of this study was determined to be unacceptable because measurements of the hematology and blood chemistry parameters, as well as the urine and ChE analyses, were performed with only 5 rats/sex/group instead of the required 8-10.

Mouse Study

There is an acceptable mouse chronic toxicity study to support registration of products containing phorate. In this study, technical phorate was administered to mice

(50/sex/group) in the diet for 78 weeks at concentrations of 1 ppm (0.15 mg/kg), 3 ppm (0.45 mg/kg) and 6 ppm (0.9 mg/kg). The histopathologic findings were considered incidental or part of the spontaneous disease process of mice and no apparent association between these findings and the ingestion of phorate was apparent. There were no consistent clinical signs that were compound-related. The only effect observed was a slight decrease in weight gain in high-dose females during the first 25 weeks of the study. Accordingly, the LEL was 6 ppm (0.9 mg/kg/day) and the NOEL was 3 ppm (0.45 mg/kg/day).

4. Oncogenicity

The rat and mouse chronic toxicity/oncogenicity studies discussed above did not reveal any evidence that phorate was oncogenic under the conditions of those studies. The rat oncogenicity study is acceptable for meeting the requirement for oncogenicity. However, based upon a reevaluation of the mouse study, the evidence does not show that an MTD was attained. The Agency is requiring a short- term mouse study to determine if any of the dietary levels administered in this study will inhibit acetylcholinesterase activity (plasma, brain and/or red blood cell). The requirement for a new mouse oncogenicity study is reserved pending the results of this special study.

5. Developmental Toxicity (Teratogenicity)

Sufficient data are available to satisfy the data requirements for teratogenicity studies in two species.

In the first study, technical phorate in corn oil was administered daily by oral intubation to pregnant rats (minimum of 23/group) from day 6 to day 15 of gestation at dosages of 0.125, 0.25 and 0.50 mg/kg. Maternal mortalities were observed in the high-dose group. An increased incidence of enlarged hearts was observed in high-dose fetuses (this cardiac enlargement is considered a transient, non-teratogenic response). No teratogenic effects were observed in this study at any dosage level. Therefore, the LEL for developmental toxicity, based on embryotoxicity, and maternal toxicity was 0.50 mg/kg and the corresponding NOEL for each was 0.25 mg/kg.

In the second study, technical phorate, in corn oil, was administered via oral gavage to groups of 20 pregnant rabbits on days 6-18 of gestation at dosage levels of 0.15, 0.5, 0.9 and 1.2 mg/kg/day. Maternal toxicity was evident at the 0.5, 0.9 and 1.2 mg/kg dosage levels, based on body weight loss during treatment and compound-induced mortality. Noted malformations were: open eyes and curved scapula in one 1.2

mg/kg litter and angulated hyoid arches in a small number of fetuses in the 0.9 and 1.2 mg/kg dosage groups. After careful consideration of these data, the Agency considers the changes to be secondary to maternal toxicity. These changes are not considered to be biologically significant under the conditions of the study. .There was no clear evidence that phorate induced a teratogenic response. The LOEL and NOEL for maternal toxicity in this study was 0.5 and 0.15 mg/kg, respectively and the NOEL for developmental toxicity was 1.2 mg/kg, the highest dosage administered.

6. Reproduction

There is an acceptable study available for technical phorate to satisfy the requirements for reproductive testing. In this study, technical phorate was administered in the diet to mice at dietary levels of 0.6 (0.09 mg.kg), 1.5 (0.23 mg/kg) and 3.0 ppm (0.45 mg/kg). Compound administration was initiated 7 weeks before the first mating. The study involved 3 generations with 2 litters (a and b) per generation. The only apparent indication of reproductive toxicity were slight reductions in the lactation and viability indices[2] in the F1b at the highest dose level. Therefore, a conservative LEL in this study was 3.0 ppm (0.45 mg/kg/day) and the NOEL was 1.5 ppm (0.23 mg/kg/day).

7. Mutagenicity

Sufficient data are available to satisfy the data requirements for mutagenicity testing. Technical phorate did not induce a genotoxic response in any of the tests listed below.

a. Gene mutation: Reverse mutation assay employing S. typhimurium, strains TA 100, TA 1535, TA 1537 and TA 1538 at dosages up to 1,000 ug/plate, with and without metabolic activation; reverse mutation in E. coli WP2(uvrA-) at dosages up to 1,000 ug/plate, in the presence and absence of metabolic activation; and test for chemical induction of gene mutation at the HGPRT locus in cultured Chinese Hamster Ovary (CHO) Cells at dosages up to 92 ug/ml, with and without metabolic activation.

b. Structural chromosome aberration tests: Dominant lethal test in mice (ICR/SIM strain) at dosages up to 20 mg/kg in the diet; and chromosome aberrations in vivo in mammalian bone marrow cells at IP dosages up to 2.5 and 1.5 mg/kg in males and females, respectively.

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[2] Viability index = number of pups alive at five days / number of pups born alive X 100. Lactation index = number of pups weaned / number of pups alive at five days X 100.

c. Tests for other genotoxic effects: Mitotic recombination of _Saccharomyces cerevisiae_ D3 at a concentration of 5%, with and without metabolic activation; preferential toxicity assays in DNA repair-proficient and -deficient strains of _E. coli_ (strains W3110 and p3478, respectively) at a level of 1,000 ug/plate; preferential toxicity assays in DNA repair - proficient and -deficient strains of _Bacillus subtilis_ (strains H17 and M45, respectively) at 1,000 ug/plate and unscheduled DNA synthesis (UDS) in human fibroblasts (WI-38 cells) at concentrations up to 10-3 M.

8. General Metabolism

Data are available from an acceptable rat metabolism study in which one dosage level was administered to male rats An additional metabolism study in female rats is required.

In this study, each of 12 male rats received a single oral dose (via gavage) of 14C-phorate suspended in corn oil. Groups of 3 animals were killed 24, 48, 96 and 192 hours after dosing. Six additional rats were dosed in the same manner in order to fully characterize various tissue metabolites. Urine, feces, liver, kidney, muscle(leg), skin, fat and blood were collected for analysis at selected post dosing time intervals.

Approximately 77.2 and 11.7% of the administered 14C was recovered in urine and feces, respectively, during the first 24-hour collection period. Total radioactivity levels in all tissues represented less than 5 and 1% of the 14C at 6 and 24 hours post dosing, respectively. Blood, skin, muscle and liver contained 4.69, 2.48, 1.94 and 1.19%, respectively, of the original dose at 6 hours after compound administration. Two of the 10 metabolites identified in urine were non-phosphorylated compounds: ethyl(methylsulfinyl) methylsulfone and (ethylsulfonyl) (methylsulfonyl) methane. These relatively non-toxic compounds comprised approximately 71% of the radioactivity present in the urine. Approximately 9 and 10% of the urinary 14C was associated with the oxidative organo-phosphorous metabolites O, O,-diethyl S-(ethylsulfonyl) methyl phosphoro thioic acid and (ethylsulfinyl) methyl, methyl sulfone, respectively. Unchanged parent compound accounted for only 0.5% of the recovered urinary 14C and the remaining phosphorylated compounds plus one unidentified metabolite collectively comprised less than 10% of the urinary radioactivity. The identified oxidative, phosphorylated compounds were: 1) Phosphorodithioic acid, O,O-diethyl _S_-(ethylsulfonyl) methyl; 2) Phosphorothioic acid, _O,O_ diethyl _S_-(ethylsulfinyl) methyl; 3) Phosphorodithioic acid, _O,O_ diethyl _S_-(ethylsulfinyl) methyl; and 4) Phosphorothioic acid, *O*,*O*-diethyl S-(ethylthio)methyl ester. The proportions of phosphorylated and non-phosphorylated metabolites in individual tissues were similar to those observed in urine.

A comparable study in female rats is required. The administration of a single dosage level in the male rat study is acceptable since the high acute oral toxicity of this compound does not allow much flexibility in dosage selection; a lower dose level might be detrimental to quantitative work with minor metabolites while a higher dose might cause mortalities. However, since females are generally more sensitive to adverse effects from phorate than males, it may be necessary to administer a lower dosage level to females than that (0.8mg/kg) given to males.

9. Special Studies

a. Phorate sulfoxide (metabolite)

Phorate sulfoxide was administered to rats (35/sex in treated groups and 50/sex in the control group) at dietary levels of 0.32 ppm (0.016 mg/kg), 0.80 ppm (0.040 mg/kg) and 2.0 ppm (0.10 mg/kg) for 90 days. Sporadic inhibition of RBC and plasma ChE activity was observed in females at the 0.8 ppm level. RBC, plasma and brain ChE activity were each inhibited in females while marginal inhibition of RBC and plasma ChE activity was noted in males at 2.0 ppm. No other dosage-related adverse effects were reported in this study. The NOEL and LEL in this study, based on inhibition of ChE activity, were 0.32 (0.016 mg/kg) and 0.8 ppm (0.04 mg/kg) respectively.

Phorate can be metabolized to more potent anticholinesterase compounds through oxidative desulfuration and/or sulfide oxidation. The oxidation products include the sulfoxide and sulfone derivatives of phorate and phorate oxygen analogue. However, findings of the rat metabolism study showed that the oxidative, phosphorylated products represented a minor proportion of the phorate metabolites measured in tissues, feces and urine. Additional toxicity studies with the oxidative metabolites may be required, if significant residue levels are detected in the required residue studies.

b. Toxic Effects on the Eye

In Japan, organophosphate pesticides have been observed to produce toxic effects on the eye. In the 1950's and 1960's, Japanese workers noted extensive human poisoning by organophosphate pesticides producing a syndrome of effects on vision ranging in severity from myopia to congestion or atrophy of the optic nerve. The Japanese researchers were able to duplicate the effects on refraction in an experimental study on dogs utilizing the organophosphates fenitrothion and ethylthiometon. Experimental studies with the organophosphate fenthion on rats by another Japanese scientist demonstrated a syndrome of toxic effects on the eye beginning with functional abnormalities in electrical activity and culminating in retinal degeneration following chronic dosing. In addition, the Agency has received reports of chronic studies of ethyl and methyl parathion in rats which demonstrated retinal atrophy.

Since phorate is an organophosphate, special acute and subchronic eye studies are required to investigate its potential systemic toxicity to eyes.

10. Pesticide Incidents

Based on data obtained from California (the only State which enforces mandatory reporting of occupational pesticide incidents and, at present, the only reliable source of information), physicians treated an average of 3.1 phorate poisonings each year from 1980 through 1986. An additional 0.4 cases per year were reported as either due to skin or eye injury. Of the total 25 illnesses reported in this period, 3 were applicators, 5 were due to exposure to residues or drift, 7 were emergency response personnel, 3 were mixer/loaders, and 7 were due to other circumstances. Between 1980 and 1986, there were 2 reported hospitalized cases of occupational phorate poisoning.

Data for 1980 through 1986 from California were examined to determine the number of applications reported by licensed pest control operators and all applications of restricted chemicals, which must be reported under California law. Data were examined for 45 selected insecticides and a ratio was calculated based on the number of poisonings per 1000 applications.

For phorate, there were 0.8 poisonings per 1000 applications reported during the time period 1980 to 1986. The average value for all 45 pesticides was 0.5, the median was 0.3. The majority of poisonings occurred in the first half of the 1980-86 time period. During the second half of this time period, phorate was responsible for 0.3 poisonings per 1000 applications. The data indicate that phorate had a slightly above average potential to produce systemic cholinesterase depression poisonings during the period 1980 to 1986.

11. Worker Exposure

In the 1984 Standard, the Agency expressed concern regarding dermal and inhalation exposure to handlers and other workers subject to continual exposure to granular formulations should the granules fracture during shipping and handling. A product integrity study on a typical end-use granular formulation was required to assess this possibility.

A product integrity study was submitted for a 20G (granular) formulation. This study showed that the potential airborne level of respirable particles was not significant. Based on the results of this study, the Agency has concluded that the 20G granular formulation does not pose an inhalation hazard under normal use conditions. A study of this type would not be expected to provide useful information on dermal exposure. Phorate is highly toxic by the dermal route of exposure. The Agency believes that the revised and updated protective clothing statements required under this Standard will adequately protect individuals against any potential hazard resulting from dermal exposure.

C. ENVIRONMENTAL CHARACTERISTICS AND EFFECTS

1. Ecological Effects

In the 1984 Phorate Registration Standard, the Agency required submission of various studies. An update on the ecological effects profile is provided below.

Avian and Mammalian Testing

Based on acceptable laboratory data, technical phorate is characterized as very highly toxic to birds on an acute oral basis and highly toxic to birds on a subacute dietary basis. The LD_{50} values range from 0.62 for mallard duck to 12.8 mg/kg for chukar. Upland game birds appear to be slightly less sensitive on an acute basis than waterfowl or songbirds. However, all classes of birds have been killed by exposure to phorate in agricultural fields, as indicated in field tests. On a dietary basis, technical phorate is highly toxic to birds with reported LC_{50} values ranging from 248 ppm for waterfowl to 441 ppm for upland gamebirds.

An avian reproduction study showed that long-term dietary exposure of 60 ppm technical phorate significantly impaired the ability of mallard ducks to produce a normal number of eggs and offspring. Data on the bobwhite quail were determined to be unacceptable, since the production of eggs in 25% of the control pairs of bobwhite was significantly below normal. A new study using bobwhite quail is required. Since there are still gaps in the environmental fate data base for phorate and its degradates, the probability of reproductive effects occurring in the field cannot be predicted. It may be that under flooded conditions phorate is more persistent. If the required anaerobic soil metabolism and other environmental fate data indicate that phorate is more persistent in flooded areas (e.g. wetland), then a field study to examine reproductive effects in waterfowl residing in wetland areas will be necessary.

There is sufficient information to characterize technical phorate as very highly toxic to small mammals on a dietary basis, with a reported LC_{50} value of 28 ppm.

In simulated field studies using a 20 percent granular (20 G) formulation applied to cornfields at rates of 1.33 and 2.62 lb ai/A, a significant number of mortalities in bobwhite quail and wild songbirds occur. In addition, there was a significant depression in the amount of brain ChE in birds that ingested the granules. In an avian pen field test in which a 10G formulation was applied at rates of 0.05 and 0.3 lb ai/A, pheasants were not affected at the lower rate. There was a 3% mortality rate at the higher rate. In another study in which a 10G formulation was applied to fields of beets and brussels sprouts at rates of 1.5 and 2.3 lb ai/A to beets and 1.5 ai/A to brussels sprouts, a dead vole, linnet, and partridge were found on the fields of brussels sprouts. The gut contents of the vole and partridge contained 0.25 and 0.05 ppm phorate residues, respectively. No dead animals were found in the beet fields.

The 1984 Standard required submission of terrestrial field testing (Level 1) because of phorate's high acute toxicity and reported kills. In response to the Standard, a screening-type terrestrial field study was conducted in which a 20G formulation was applied to corn by three different methods of application (banded at-planting, band at cultivation, and aerial over the plants). Bird carcasses were found in each phase of the study. This study also resulted in mammalian mortality under each application technique. The data indicate that residues of phorate and its degradates appear to be toxic to birds and mammals for as long as 2 to 3 weeks. Aerial application appeared to be more hazardous than soil application.

Risk to Terrestrial Organisms

The Agency is concerned about the risk to avian species posed by the use of granular pesticides, including phorate. In addition to indirect exposure from pesticide residues on avian feed items, birds may be directly exposed to the pesticide by ingesting pesticide granules as they forage for food and grit on the soil, thus consuming discrete doses of phorate.

To evaluate this risk, the Agency evaluated both toxicity and exposure.

Toxicity

As indicated under "Avian and Mammalian Testing", laboratory studies have demonstrated that phorate is very highly toxic to birds on an acute oral basis (LD_{50}) and highly toxic to birds on a dietary basis (LC_{50}). Toxicity was further analyzed by estimating the number of granules, that, if ingested by a bird, would be equivalent to its LD_{50}. The LD_{50} value was chosen for toxicity analysis because birds encounter granules as discrete doses, which is similar to the type of exposure in a laboratory LD_{50} test. The following factors were considered in this toxicity analysis: (1) LD_{50} values, (2) average body weights of birds, (3) weight of the granule or reasonable estimate of its weight, and (4) percent active ingredient (a.i.).

The results of this analysis indicate that the following number of granules would be equivalent to the LD_{50} from the phorate 15G and 20G formulations:

	Waterfowl	Songbird	Game
15G	49	4	99
20G	10	1	21

Based on the literature (Balcomb 1980, Wentworth 1968, Bent 1963 and Kenaga 1974), the Agency estimates that 0.1% to 1.0% of the daily food intake of a bird is in the form of grit and seeds. If pesticide granules are available, they will comprise part of this grit and seed consumption. Based upon this range for intake, the average body weights of birds and the median weight of a pesticide granule, it is estimated that waterfowl may pick up 120 to 1200, gamebirds 53 to 530 and songbirds 25 to 250 pesticide granules. However, limited field reports suggest that birds are not likely to consume more than 50 pesticide granules.

Using this consumption limit of 50 pesticide granules, the table above indicates that birds can readily consume an $LD5_0$ dose of phorate, with the exception of upland gamebirds consuming phorate 15G. This shows that birds can reasonably consume enough phorate granules to die.

Exposure

Many different species of birds may be present when phorate is applied. These birds may be exposed to phorate granules when they feed on avian food items containing phorate residues. They may also consume the granules directly while foraging for seed or dietary grit on or below the soil surface. In addition, predatory birds may be secondarily exposed to vertebrates poisoned from exposure to granular pesticides or directly from the granules themselves.

The number of granules a bird will encounter depends on the rate of application and the number of granules present on or near the soil surface. The Agency believes that all applications of phorate (at planting, banded and cultivation treatments, as well as aerial application) will result in a number of granules present at or near the surface, and thus easily accessible to foraging wildlife.

To evaluate exposure, the number of granules present after application on the soil surface was estimated. A square foot was chosen as the unit area for exposure because birds feeding on treated fields would be able to quickly search a square foot area for food or grit. For these calculations, it was assumed that 15 percent of the applied granules are present on the surface after band application (Erbach and Tellefson 1983), 1 % after in-furrow application (Hummel 1983) and 100 % after broadcast (aerial) application.

Determination of Risk

The avian risk from phorate use is dependent on both toxicity and exposure. The risk was evaluated for corn, cotton, and potatoes using the following formula:

$$\text{RISK} = \frac{\text{no. of Granules/square foot}}{\text{no. of granules equal to } LD_{50}}$$

$$= \text{no. of } LD_{50} \text{ doses/ square foot}$$

Avian risk equals the number of LD_{50} doses per square foot. If the result is equal to or greater than 1, the pesticide may pose a serious risk to birds[3]. The greater the number, the greater the risk (see Table 1 below).

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[3] Based on the results of several laboratory and field studies, DeWitt (1966) studied the relationship between the quantities of pesticide toxicant that birds ingested in the laboratory to the amount of pesticide deposited per unit area in the field during agricultural operations and concluded that birds may be expected to die if the quantity of toxicant in a square foot area equals or exceeds the amount of toxicant that causes 50% mortality in a laboratory study.

Table 1. Risk to Avian Species Based on Estimates of Number of LS_{50}'s per Square Foot for Three Sites

Formulation	lb ai/A	Method	No. of Granules on Surface	Songbirds		Waterfowl		Game Birds	
				Granules LD_{50}	LD_{50}s Sq Ft	Granules LD_{50}	LD_{50} Sq Ft	Granules LD_{50}	LD_{50} Sq Ft
Corn									
15G	1.3	Banded	683	4	174	49	14	99	7
15G	1.0	Broadcast	817	4	208	49	17	99	8
20G	1.3	Banded	145	< 1	174	10	14	21	7
20G	1.0	Broadcast	174	< 1	210	10	17	21	8
Cotton									
15G	0.5	In-furrow	49	4	13	49	1	99	< 1
15G	1.6	In-furrow	157	4	40	49	3	99	2
15G	1.6	Banded	1009	4	257	49	21	99	10
15G	2.1	Banded	1324	4	338	49	27	99	13
20G	0.5	In-furrow	10	< 1	12	10	1	21	< 1
20G	1.6	In-furrow	33	< 1	40	10	3	21	2
20G	1.6	Banded	214	< 1	258	10	21	21	10
20G	2.1	Banded	281	< 1	339	10	27	21	13
Potatoes									
15G	3.5	In-furrow	305	4	78	49	6	99	3
15G	2.1	Banded	1177	4	300	49	24	99	12
15G	3.5	Banded	1962	4	500	49	40	99	20
20G	2.1	In-furrow	49	< 1	59	10	5	21	2
20G	2.1	Banded	250	< 1	301	10	24	21	12
20G	3.5	Banded	417	< 1	502	10	40	21	20

The values in this Table indicate that sufficient granules of phorate are estimated to be present to kill significant numbers of birds feeding in agricultural fields. For songbirds and waterfowl, the number of LD50s/sq ft is greater than 1 in all cases. This prediction is corroborated by field studies and bird kill incident reports (see Table 2).

Table 2. Reported Bird Kill Incidents From Phorate

Date of Kill	State	Number and Kind of Birds Killed	Nature of Incident
11/78	California	Ring-billed gull, cattle egret, long-billed curlew (total of 195 birds)	Found dead in field treated 2 days earlier with phorate and irrigate Brain ChE activity was inhibited 92%. Ingesta contained phorate residues.
02/19/81	Fresno County, CA	2000 dead blackbirds, 2 pheasants, several pigeons	Thimet 15G was applied aerially o February 19 to wheat field. Thime residues (24 ppm) detected in gizz linings. Standing water found in irrigation ditches was believed to means of exposures.
02/22/81	Merced County, CA	100 waterfowl, 100 birds of other species as sparrows, blackbirds, killdeer, larks	Thimet 15G was aerially applied to alfalfa fields south of site where birds found. Granules found on th site. 31 to 54 ppm Thimet residue in birds.
10/82	Potter County, SD	133 mallards; 51 pintails; 46 wigeons; 36 gadwalls; 12 green-winged teals; 1 white-fronted goose; 3 Canada geese; 6 marsh hawks; 2 red-tailed hawks; and 4 great horned owls	Thimet 15G was applied at the rate 6 lb/A on the border of a winter wheat field on September 10, 1982. Birds were found in an intermitten wetland basin (4 to 5 acres, 6 to inches deep) several days after he rains. Two empty bags of Thimet w in the area. Water and sediment samples were collected October 18. Mean Thimet residues of 1 ppb in water and 15 ppb in sediment; mean Thimet sulfoxide residues of 7 ppb water and 51 ppb in sediment.

10/82	Lyman County, SD	38 mallards; 4 gadwalls; wigeons; 6 pintails; 7 green-winged teals; 1 red-tailed hawk; and 1 golden eagle	Thimet 15G was applied to winter wheat field. Birds were found in a intermittent wetland basin (1 acre, 6 to 8 inches deep) several days after heavy rains. Two empty bags Thimet were in the area. Water and sediment sampled October 20. Mean Thimet residues of 7 ppb in water and 14 ppb in sediment; mean Thimet sulfoxide residues of 18 ppb in wate and 30 ppb in sediment.
01/16/87	Solano County, CA	Red-tailed hawk	The hawk was found in stressed condition in a mud field and died at a rehabilitation facility. Severe brain ChE depression. Fecal materia contained residues of phorate-type C and phorate was being used in area. Death was attributed to phorate.
11/04/86	Tulelake, CA	50 mallards, 50 pintails	Birds were found on agricultural lan and deaths were attributed to phorate.
02/16/87	Jefferson County, ID	Bald eagle	Death attributed to phorate.
12/05/82	Potter County, SD	Bald eagle	Suspected phorate poisoning.

Aquatic Organisms Testing

Based on acceptable laboratory data, technical phorate is characterized as very highly toxic to freshwater fish and invertebrates. The LC_{50} values were 6 to 13 ppb for trout (coldwater fish), 2 to 5 ppb for bluegills and bass (warmwater fish), 280 ppb for catfish (warmwater fish), 0.68 ppb to 9 ppb for amphipods and stoneflies, and 50 ppb for decapods. Technical phorate is very highly toxic to estuarine fish and invertebrates. The EC_{50} ranges are 0.11 to 1.9 ppb for shrimp and 1.3 to 5.0 ppb for spot and sheepshead minnow. The EC_{50} value for mollusks is 900 ppb. A study in which the inhibition of brain AChE was determined in adult sheepshead minnows indicates that prior to death AChE activity falls below 17.7 percent of normal following exposure to lethal concentrations.

One study on the early life stage of estuarine fish indicates that 0.41 ppb is significantly toxic to juveniles for an exposure period of 28 days postfertilization. The maximum acceptable toxicant concentration (MATC) is between 0.24 and 0.41 ppb. A study on the life cycle of shrimp indicates that 28-day survivability is significantly reduced at 0.21 ppb. The MATC is between 0.09 and 0.21 ppb. These studies are deficient as the raw data were not submitted as required in the 1984 Standard. If the data are unavailable, new studies are required. An early life stage study with freshwater fish was determined to be unacceptable because of the high mortality in the control fish embryos (>50%). A new study is required. An invertebrate life cycle study is incomplete. The raw data must be submitted. If the data are unavailable, a new study is required.

There is sufficient information to characterize a 20G formulation as very highly toxic to freshwater fish and invertebrates. The LC50 values were 45 ppb for rainbow trout, 12 ppb for bluegill and 2200 ppb for channel catfish. The LC50 values for invertebrates ranged from 37 ppb for daphnids to 65 ppb for mayfly nymphs. The 20G formulation ia also very highly toxic to estuarine fish and invertebrates. The LC50 values are 8.2 ppb for sheepshead minnow; 1.4 ppb for shrimp; and 17 ppb for oysters.

Based on phorate's very high toxicity to aquatic organisms, high levels of phorate measured in ponds and reports of fish kills (see Table 2), an aquatic field study was required in the 1984 Standard. This study is currently in progress (see discussion under Hazards below).

Risk Assessment for Aquatic Organisms

Aquatic organisms may be at risk from exposure to phorate via its terrestrial uses (run-off and drift).The laboratory toxicity data indicate that phorate is very highly toxic to freshwater and estuarine fish and invertebrates. Based on one reported incident in Illinois in 1970, a significant amount of phorate and its degradates were present in the water of ponds that received the surface runoff from rainfall following applications of phorate to cornfields. Residue concentrations in the three ponds ranged from 6.8 to 32.3 ppb 2 weeks after the application. Several days after the applications and heavy rainfalls, dead fish, predominantly bass and bluegill, were observed in the ponds. An estimated 2000 to 3000 died within one pond alone. Although the cornfields were also treated with pesticides other than phorate, the deaths were attributed to phorate, since the measured residues were greater than the LC_{50} values for some warmwater fish and phorate is more toxic than the other pesticides identified in this incident.

Although there are no acceptable fish and invertebrate chronic toxicity data, the estuarine fish and shrimp data

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Although there are no acceptable fish and invertebrate chronic toxicity data, the estuarine fish and shrimp data indicated that survivability was significantly reduced at phorate concentrations <0.41 ppb. Residue levels of 0.4 to 0.6 ppb were measured in two of the ponds approximately 6 weeks after treatment, and 12.1 ppb phorate was measured in the third pond 37 days postapplication following seven rainfall events. These residue values indicate that phorate is present at levels that can kill aquatic organisms acutely or produce long-term population effects.

These data, including the fish kill reports and residue data, were originally reviewed in the 1984 Standard. Based on these findings, a field study was required to measure the effects of phorate on the stability of aquatic ecosystems and populations. A 2-year pond study is currently in progress in the corn region of Iowa[4]. Following the completion of this study and other data required in this Standard, an assessment of aquatic risks can be completed.

Honeybee Acute Toxicity

There is little or no exposure expected to beneficial insects resulting from phorate granular formulations. No data are required.

Endangered Species

Because of the demonstrated toxicity of phorate to nontarget fish, aquatic invertebrates, birds, and mammals, phorate was identified by the U.S. Fish and Wildlife Service (USFWS) as likely to jeopardize endangered animal species, including endangered insects, when used on crops. Based on this determination, USFWS specified reasonable and prudent alternatives to avoid jeopardizing the continued existence of the identified species by these uses. EPA is working with USFWS and other Federal and State agencies to implement the alternatives in a technically sound manner.

2. Environmental Fate

In the 1984 Registration Standard, the Agency required a full battery of environmental fate testing, except for spray drift data. Subsequent to the issuance of the Registration Standard, all registrants withdrew phorate's sole aquatic food use on rice, and as a result, study requirements triggered by aquatic food crop use (anaerobic aquatic metabolism, aerobic aquatic metabolism, aquatic soil dissipation, accumulation in aquatic nontarget organisms, and accumulation in irrigated crops) were no longer required.

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[4] The study design is based on comparing two reference ponds with two ponds that will receive runoff containing residues of phorate. A base-line study is currently in progress to gather data on the natural populations in the ponds and to characterize the abiotic components of the ponds such as productivity and respiration. In 1989 the cornfields surrounding the two treatment ponds will be treated with an at-planting application and, later in the season, with an aerial broadcast application.

The data submitted in response to the 1984 Standard have been reviewed and, with the exception of leaching and absorption/desorption, do not fulfill the data requirements. An update on the environmental chemistry profile is as follows:

Leaching and Adsorption/Desorption Studies

Based on acceptable batch equilibrium studies, ^{14}C phorate was very mobile to mobile in loamy sand, sandy loam, silt loam, and loam soils. K_{ads} values calculated using the Freundlich equation were 1.53 for loamy sand soil, 3.13 for the sandy loam soil, 7.54 for the silt loam soil, and 19.9 for the loam soil. These Freundlich K_{ad} values determine the mobility of the pesticide and its degradates in different types of soil. Soil/solution partition coefficient values (K_{OC}) were 450, 505, 512, and 705 for the loamy sand, sandy loam, silt loam, and loam soils, respectively, and soil distribution coefficient (K_d) values obtained following desorption were 2.53, 5.25, 4.10, and 13.2.

Aged (10 days) residues of ^{14}C phorate were mobile in 24-inch columns of sandy loam and loamy sand soil and were slightly mobile in 21-inch columns of silt loam and clay loam soil. Only low levels of phorate were detected in the leachates. Phorate sulfoxide and phorate sulfone were only detected in the leachates from the sandy loam and loamy sand soil columns. In the sandy loam and sandy soil columns, phorate and the degradate phorate sulfoxide accounted for approximately 35 to 68 and 20 to 36 percent of the applied radioactivity, respectively. Phorate sulfone was detected primarily in the silt loam and clay loam soil columns and accounted for approximately 10 and 30 percent of the applied radioactivity in these soils. Phorate sulfone was 0.8 percent of the applied ^{14}C phorate in the loamy sand and sandy loam soils.

Aerobic Soil Metabolism Studies

Based on preliminary data, [^{14}C]phorate degraded with a half-life of <3 days in sandy loam soil. Phorate declined from 0.85 ppm at 0 days posttreatment to 0.16 ppm at 6 days posttreatment, then to 0.00 ppm (detection limit not reported) at 31 days posttreatment. The degradate phorate sulfoxide reached a maximum concentration 0.62 ppm at 6 days posttreatment, then declined to 0.08 ppm at 120 days posttreatment. Phorate sulfone reached a maximum concentration of 0.66 ppm at 31 days posttreatment and then declined to 0.57 ppm at 120 days posttreatment.

This study will be acceptable conditioned upon submission of freezer storage stability data and specification of the purity of the test substance. Otherwise, a new study is required.

Terrestrial Field Dissipation Studies

Three studies were received by the Agency for review. In one study, phorate dissipated with a half-life of <3 days from the upper 3 inches of two field plots of sandy loam soil following application of phorate. The calculated half-life was 2 days. Phorate declined from 1.01 to < 0.05 ppm in the 0- to 3-inch soil depth, maximum concentrations of phorate sulfoxide and phorate sulfone were 0.26 ppm (day 7 posttreatment) and 0.11 ppm (day 15 posttreatment), respectively, and declined to < 0.05 ppm by day 60 posttreatment.

At a site in Illinois, phorate dissipated with a half-life of 9 to 15 days from the upper 3 inches of two field plots of silt loam soil following the application. The calculated half-life (derived from the residue decline curve plotted on a graph) was 19 days. Phorate declined from a maximum of 0.75 ppm at 3 days posttreatment to < 0.05 ppm by 59 days posttreatment in the 0- to 3-inch soil depth. At all other soil depths (down to 18 inches), phorate concentrations were < 0.05 ppm throughout the study. In the 0- to 3-inch phorate soil depth, maximum concentrations of phorate sulfoxide and phorate sulfone were 0.73 ppm (day 30 posttreatment) and 0.42 ppm (day 30 posttreatment), respectively, and declined to 0.05 and 0.26 ppm by day 180 posttreatment. Phorate sulfoxide and phorate sulfone were < 0.05 ppm at all other soil depths. Phorate oxygen analogue was < 0.05 ppm at all sampling intervals.

At a site in Iowa, phorate dissipated with a calculated half-life of 12 days in silt loam soil treated with phorate, declining from 10.2 ppm immediately posttreatment to 5.34 ppm by day 7, to 0.25 ppm by day 30, and to < 0.05 ppm by day 92. Phorate was < 0.05 ppm in the 3- to 6-, 6- to 9-, and 9- to 12-inch sampling depths at all sampling intervals. In the 0-to 3-inch soil depth, phorate sulfoxide declined from a maximum of 2.92 ppm at 7 days posttreatment to 0.18 ppm at 180 days posttreatment. Phorate was < 0.05 ppm at all sampling depths and intervals except for day 30 in the 6-to 9-inch depth (0.06 ppm). In the 0- to 3-inch depth, phorate sulfone reached a maximum of 1.93 ppm at 60 days posttreatment and declined to 0.13 by day 180. In the 3- to 6-inch depth, phorate sulfone reached a maximum of 0.16 at 180 days. Phorate sulfone was < 0.05 ppm at all sampling intervals at the lower depths except at day 30 in the 6- to 9-inch depth (0.07 ppm). Phorate oxygen analog was < 0.05 ppm at all sampling depths.

These studies will be acceptable conditioned upon submission of freezer storage stability data of phorate and its degradates of samples frozen prior to analysis. Otherwise, a new study must be conducted.

Accumulation in Confined Rotational Crops Studies

[^{13,14}C]Phorate residues accumulated in lettuce, corn, and a root crop planted 1, 3, and 12 months after [^{13,14}]phorate was applied to sandy loam soil. Maximum accumulation occurred in crops planted at 1 month posttreatment; [^{13,14}C]residues at harvest were 0.47 ppm in lettuce; 0.75 and 0.53 ppm in beet tops and roots; and 0.32, 0.03, and 0.02 ppm in corn fodder, kernels, and cobs. In crops planted at 3 and 12 months posttreatment, total [^{13,14}C]residues at harvest were 0.03 ppm in lettuce, 0.05 to 0.06 and 0.02 to 0.03 ppm in radish tops and roots, up to 0.02 ppm in corn fodder, and below 0.01 in corn kernels and cobs. Parent phorate was detected in corn plants (o.016 ppm) and beet tops .063 ppm), but not in beet roots or lettuce. The primary degradate in all crops was the nonphosphorylated disulfone. Other degradates detected included phorate sulfone and phorate sulfoxide.

[^{13,14}C]Phorate residues dissipated with a half-life of 1 to 3 months from the upper 3 inches of sandy loam soil. At 12 months posttreatment, [^{13,14}C]residues were detected at 0.18 ppm at the 0- to 3-inch soil depth and at 0.01 ppm or less at lower soil depths. Parent phorate accounted for <2 percent of the extractable radioactivity from any soil sample. The primary degradate in the soil was phorate sulfone, which accounted for 72% (0.748 ppm), 75% (0.074 ppm), and 29% (0.012 ppm), respectively of the extractable radioactivity from the 1-, 3-, and 12-month soil samples, respectively. Other degradates detected include nonphosphorylated disulfone, phorate sulfoxide, and several unknowns.

This study only partially satisfies the requirement for a confined rotational crop study, because not all of the test substances (phorate, phorate sulfoxide and phorate sulfone) were completely characterized and, except for one sampling interval, the residues in the soil were not analyzed at the time of harvest of the rotational crop. Also, the study was conducted with 1.5 lb ai/A instead of the maximum label rate. If this missing information is submitted and determined to be acceptable by the Agency, the study will only be adequate to support a maximum label rate of 1.5 ai/A. Alternatively, the registrant may choose to conduct a new study.

No data were submitted for field rotational crops. However, the Agency is now reserving this requirement pending the results of the confined rotational crop study.

Fish Accumulation Studies

A fish accumulation study submitted in response to the 1984 Standard was reviewed and determined to be unacceptable since the test substance was incompletely characterized, the fish may have only been exposed to the parent compound, and degradate characterization results from the fish tissue samples were reported in terms of percent recovered radioactivity from the TLC plates rather than percent of total (initial) sample radioactivity. A new study is required.

Groundwater

The 1984 Registration Standard indicated that phorate has some potential to leach through the soil and contaminate ground water. Based on recently submitted data, phorate does not appear to be a potential leacher. However, its sulfone and sulfoxide degradates show greater persistence and mobility in soil, and therefore may have a greater leaching potential. Due to inadequate information on aerobic/anaerobic soil metabolism and field dissipation of phorate and its degradates, the requirement for groundwater monitoring studies is deferred at this time. However, a terrestrial field dissipation study is required to be conducted on sandy loam soil in Long Island, New York. Depending on the results of this and other required environmental fate studies, the need for ground water monitoring studies will be determined.

D. TOLERANCE REASSESSMENT

1. Tolerances Issued

Tolerances for residues of phorate in or on food and feed commodities are published in 40 CFR 180.206. A tolerance for residues of phorate on the processed feed commodity, dried sugarbeet pulp, is published in 21 CFR 561.290. Tolerances are expressed in terms of phorate and its cholinesterase-inhibiting metabolites. EPA has evaluated the residue and toxicology data supporting these tolerances based on data submitted in response to the 1984 Standard. The following were considered during this evaluation:

- Whether the current tolerances and food additive regulations are sufficient to cover the actual residues resulting from use (including FIFRA section 24(c) uses).

- Whether group tolerances can be established in accordance with 40 CFR 180.34(f).

- Whether, in the absence of tolerances, restrictions on use, grazing, or feeding of treated commodities are necessary.

- Whether the tolerances are expressed accurately and in the current terminology.

The Agency's findings as a result of this evaluation are summarized below. The regulatory results of the Agency's review are set out in Section IV Regulatory Position and Rationale.

2. Residue Data

An update on the residue chemistry data in support of phorate tolerances is as follows:

a. The nature of the residue in plants is adequately understood and no additional data are required. The metabolites of phorate in plants are listed in Table 3. The available evidence indicates that phorate is metabolized in plants by oxidation of the thioether sulfur and then the thiono sulfur to yield the organosoluble metabolites II, III, V, and VI. Varying smaller amounts of the water-soluble metabolites X-XIII occur as a result of hydrolysis of the sulfoxide and sulfone metabolites. Although the metabolism of phorate in plants is well documented, particularly with respect to bean plants, it is noted that all of the in-depth plant metabolism studies employed [^{32}P]phorate rather than [^{14}C]phorate, and could not detect the dephosphorylated metabolites VII, VIII, and IX found in ruminants, if they indeed occur (see under b below). However, the Agency has concluded that these metabolites are not of toxicological concern, and therefore the metabolism of phorate in plants is adequately understood. No additional data are required.

Table 3. Phorate and its Metabolites in Plants and Animals

	Common Name and Chemical Name	Found In:
I.	Phorate O,O-diethyl S-[(ethylthio)methyl]phosphorodithioate	Alfalfa leaves
		Bean leaves
		Carrot roots
		Corn foliage
		Cotton leaves
		Cotton leaves
		Cotton leaves
		Oat foliage
II.	Phorate sulfoxide O,O-diethyl S-[(ethylsulfinyl)methyl]-phosphorodithioate	Alfalfa leaves
		Bean leaves
		Carrot roots
		Corn foliage
		Cotton leaves
		Cotton leaves
		Cotton leaves
		Lemon leaves
		Oat foliage
		Pea foliage
		Potato tuber
		Radish root
III.	Phorate sulfone O,O-diethyl S-[(ethylsulfonyl)methyl]-phosphorodithioate	Alfalfa leaves
		Bean leaves
		Carrot roots
		Corn foliage
		Cotton leaves
		Lemon leaves
		Pea foliage
		Potato tuber
		Radish root
IV.	Phorate oxygen analog O,O-diethyl S-[(ethylthio)methyl] phosphorothiolate	Carrot root
		Potato tuber
		Radish root
		Goat milk, tissue

Table 3. Phorate and its Metabolites in Plants and Animals

	Common Name and Chemical Name	Found In:
V.	Phorate oxygen analog sulfoxide 0,0-diethyl S-[(ethylsulfinyl) methyl]phosphorothiolate	Alfalfa leaves Bean leaves Carrot roots Corn foliage Cotton leaves Lemon leaves Oat foliage Pea foliage Potato tuber Radish root Goat milk, tissue
VI.	Phorate oxygen analog sulfone 0,0-diethyl S-[(ethylsulfonyl)methyl]phosphorothiolate	Bean leaves Carrot roots Corn foliage Cotton leaves Lemon leaves Oat foliage Potato tuber Radish roots Goat milk, tissue
VII.	(ethylsulfonyl)(methylsulfonyl)methane	Goat, milk tissue
VIII.	(ethylsulfinyl)(methylsulfonyl)methane	Goat, milk tissue
IX.	(ethylsulfonyl)(methylsulfinyl)methane	Goat milk, tissue
X.	Phosphoric acid	Bean leaves Cow urine

Table 3. Phorate and its Metabolites in Plants and Animals

Common Name and Chemical Name	Found In:
XI. O,O-diethyl phosphoric acid	Bean leaves Cotton leaves
XII. O,O-diethyl phosphorothioic acid	Bean leaves Cow urine

b. The nature of the residue in animals is not totally understood. Metabolism studies utilizing poultry are required. No additional data are required for ruminants (cows and goats). The metabolites of phorate in ruminants are listed in Table 3. In ruminants fed radiolabeled ^{14}C phorate[5], cleavage of the sulfur-phosphorus bond of phorate (I), methylation of the resulting mercaptan to a sulfide, and oxidation resulted in the formation of metabolites VII, VIII, and IX. These metabolites comprised 94-99.5% of the recovered radioactivity in goat milk and tissues. In contrast, phorate (I) and its phosphorylated metabolites (II-V) collectively accounted for <0.2% of the recovered radioactivity in milk and <0.01-1.5% in tissues. The dephosphorylated metabolites (VII, VIII, and IX) have not been identified in plant metabolism studies; however, those studies employed [^{32}P]phorate rather than [^{14}C]phorate. The Agency has determined that these metabolites are of no toxicological concern.

c. Validation data and/or descriptions of analytical methods are required for various procedures submitted by American Cyanamid to determine their suitability for data collection and enforcement purposes. The validation data must reflect separate fortifications of phorate and its sulfoxide, sulfone, oxygen analog, oxygen analog sulfoxide and oxygen analog sulfone for each commodity tested.

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[5] In the 1984 Standard it was concluded that the nature of the residue in animals was not adequately understood. Additional data on the metabolism of [^{32}P]phorate, [^{32}P]phorate sulfoxide, and [^{32}P]phorate sulfone by ruminants were required. The Agency subsequently reassessed the animal metabolism data and determined that metabolism studies using [^{14}C]phorate alone would suffice.

d. Data using PAM protocols I -IV are needed for phorate and metabolites sulfone, sulfoxide, oxygen analog sulfone, and oxygen analog sulfoxide in various commodities.

e. The available data support the established tolerances for the combined residues of phorate and its cholinesterase-inhibiting metabolites in or on potatoes, sugar beets, sugar beet tops, sugar beet pulp, and soybeans.

f. Data are not adequate to support many of the established tolerances for phorate. Data on the magnitude and levels of residues of phorate and its degradates in individual raw agricultural commodities, animal products, processed food andfeed items, and cooked items are required. Sample histories and storage stability data are required for various commodities.

3. Toxicology

In the 1984 Standard, a NOEL from an acceptable chronic feeding study was not available, and therefore, a provisional value for an acceptable daily intake (PADI) was established on the basis of a NOEL from a subchronic (90-day) feeding study in rats. In this study, a 200-fold safety factor was used with a NOEL value of 0.66 ppm (0.033 mg/kg based primarily on RBC cholinesterase inhibition in females) to derive a PADI value of 0.000165 mg/kg and a maximum permissible intake (MPI) value of 0.0099 mg/day for a 60 kg person.

The current RfD for phorate is based upon a 1-year dog study in which technical phorate was administered in capsules to beagle dogs for 1 year at daily dosage levels of 0.005, 0.010, 0.050 and 0.250 mg/kg. The highest dosage caused slight tremors in both sexes and marginal inhibition of body weight gain in males. Plasma cholinesterase was inhibited at 0.05 mg/kg/day in both sexes; RBC and brain cholinesterase were inhibited in both sexes at 0.250 mg/kg/day. The corresponding NOELs were: systemic toxicity = 0.050 mg/kg/day, plasma cholinesterase inhibition = 0.010 mg/kg/day, RBC and brain cholinesterase inhibition = 0.050 mg/kg/day. Based on the NOEL for brain cholinesterase inhibition in this study and an uncertainty factor of 100[6], the Agency has established 0.0005 mg/kg/day as the RfD.

The Agency has performed a preliminary dietary exposure analysis using tolerance level residues and percent of crop treated where possible. The ARC for phorate for the U.S. population average is 0.000491 mg/kg/day. The ARC is based on current tolerance levels, including those commodities for which phorate is no longer registered or used (these tolerances will be revoked), and has been adjusted, where possible, based on percent of crop treated. For the U.S. population average, the ARC occupies 98% of the ADI. For children 1 to 6 years of age, the ARC occupies 235% of the ADI, and for non-nursing infants, it occupies 331% of the ADI. · Due to the significant contribution made by milk to the diet of children and non-nursing infants, data regarding the reduction of residues through processing (pasteurization) are required. EPA believes that residues in pasteurized milk will be significantly lower than in raw milk. and that dietary exposure of children and infants to phorate will be concomitantly lower. In addition, processing studies are required for potatoes, corn, sorghum, wheat, and sugarcane, and cooking data are required for potatoes, red meat, poultry and eggs. Cooking and processing of RACs are expected to signifi cantly reduce phorate residues in the diet.

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[6] An uncertainty factor of 100 was used, since systemic toxicity was observed at the NOELs for RBC and brain cholinesterase.

E. REFERENCES CITED IN THE SCIENCE ASSESSMENT

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IV. REGULATORY POSITION AND RATIONALE

A. SUMMARY OF REGULATORY POSITIONS AND RATIONALES

Based on review and evaluation of all available data and other relevant information on phorate, the Agency has made the following determinations:

1. The Agency is conducting a comparative avian risk assessment of various granular pesticides including phorate. Based on this assessment, regulatory action may be taken.

Rationale: Based on a high acute toxicity of phorate to avian species and the current registered use patterns of phorate, there is a high potential for adverse effects to avian species from exposure to phorate granules at or near the soil surface. This potential for exposure to phorate is demonstrated from results of Level I studies and is confirmed by bird kill incidents. The Agency is currently evaluating these data in the context of a comparative risk assessment of granular pesticides which may pose a risk to birds. Based on this assessment, the Agency will determine whether regulatory action should be taken.

2. The Agency will assess the hazards to aquatic organisms upon receipt of an aquatic organism field study. At this time the Agency will determine whether further regulatory action is necessary.

Rationale: Available field reports and laboratory data indicate that the concentrations of phorate in the aquatic environment resulting from the registered uses of phorate might expose aquatic species to residue levels exceeding risk criteria for Special Review. (Refer to Section C.3. in Chapter III of this document for a discussion of the potential risks to aquatic organisms.) In the 1984 Standard, the Agency required submission of an aquatic field study to assess potential risks to aquatic organisms. The aquatic organism study is currently underway and is due by 1991. Upon receipt and evaluation of the aquatic organism field study, a determination will be made regarding whether regulatory action, including a Special Review, is warranted.

3. The USFWS has determined that certain uses of phorate, including uses on corn and sorghum, may jeopardize the continued existence of endangered species. EPA is developing a program to reduce or eliminate exposure to these species to a point where use does not result in jeopardy, and will issue notice of any necessary labeling revisions when the program is developed. No additional labeling is required at this time. Labeling requirements issued in PR Notices 87-4 and 87-5 have been withdrawn.

Rationale: Because of the demonstrated toxicity of phorate to nontarget fish, aquatic invertebrates, birds, and mammals, phorate was identified by the USFWS as likely to jeopardize endangered animal species, including endangered insects, when used on crops. Based on this determination, USFWS specified reasonable and prudent alternatives to avoid jeopardizing the continued existence of the identified species by these uses. EPA is working with USFWS and other Federal and State agencies to implement the alternatives in a technically sound manner.

In order to reduce or eliminate exposure to these species to a point where use does not result in jeopardy, EPA required special labeling on end-use products of phorate under PR Notices 87-4 and 87-5. Subsequent issuance of PR Notice 88-1 withdrew PR Notices 87-4 and 87-5 pending development of a more focused program to protect endangered species from adverse effects in the use of pesticides. When the program is fully developed, notice of any labeling necessary to protect endangered species will be issued.

4. In order to meet the statutory standard for continued registration, the Agency has determined that phorate products must bear revised and updated labeling for hazards to nontarget organisms. Refer to Section V for the wording of these statements.

Rationale: Label statements are required since available data show that phorate is very highly toxic to birds, mammals and aquatic organisms, and highly toxic to mammals.

5. The Agency is requiring submission of special acute and subchronic eye studies.

Rationale: Studies available to the Agency have implicated some of the organophosphates in causing effects such as retinal degeneration and myopia. Because of this concern (refer to Section IIIB for a discussion), the Agency is now requiring submission of special acute and subchronic studies, such as electroretinogram and direct corneal measurements. The data will provide the information necessary to confirm or deny the potential for phorate to cause retinal degeneration and myopia in the human eye. Pending receipt and evaluation of these studies, the Agency will determine whether labeling modifications or other regulatory action is warranted.

6. The Agency will not approve significant new food uses[7]

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[7] "New use" is defined in 40 CFR 152.3(p). In the case of a new food or feed use, the Agency will generally consider as significant an increase in the TMRC of greater than 1%.

for phorate until residue data sufficient to perform a tolerance reassessment have been submitted.

Rationale: In the 1984 Standard, the Agency expressed concerns about the human dietary exposure to phorate and its metabolites and considered initiating Special Review, but withheld action pending receipt of metabolite toxicity and residue chemistry data to evaluate the magnitude of human dietary exposure to phorate and its metabolites. Based on data submitted under this Standard, the Agency no longer believes that phorate will cause adverse effects to humans for the reasons given below.

a. The Anticipated Residue Contribution (ARC) for the U.S. population average is 0.000491 mg/kg/day, corresponding to 98% of the RfD (for children 1 to 6 years of age, the ARC occupies 235% of the RfD, and for non-nursing infants, the ARC occupies 331% of the RfD). This is considerably lower than the calculations derived from available data in the 1984 Standard, in which the TMRC to the human diet represented 1030.71% of the PADI. Due to the significant contribution made by milk to the diet of children and non-nursing infants, data regarding the reduction of residues through processing (pasteurization) are required. In addition, processing studies are required for potatoes, corn, sorghum, wheat, and sugarcane, and cooking data are required for potatoes, red meat, poultry and eggs. The Agency expects that cooking and processing of meat and milk will reduce residues of phorate to levels which will be of little or no concern.

b. Plant metabolism studies reviewed by the Agency for the 1984 Standard indicated that the major portion of the residues of phorate consisted of the oxidation products, sulfone and sulfoxide. However, based on limited acceptable residue data submitted in response to the 1984 Standard, the combined levels of phorate and its oxidation products have been shown to be very low. However, many of the tolerances for phorate are still not adequately supported. Additional data (residue studies, processing and cooking studies, residue analytical methods, poultry metabolism study and storage stability data) are needed before the Agency can determine the adequacy of current tolerance levels and perform a tolerance reassessment. Because of these extensive residue chemistry data gaps, significant new uses will not be granted until these data gaps have been filled.

7. The Agency is imposing a 48-hour reentry interval for all uses of phorate on an interim basis pending submittal and evaluation of required reentry data. Based upon foliar and soil dissipation studies, registrants must propose a reentry interval in accordance with the Pesticide Guidelines, Subdivision K.

Rationale: Data are not available to establish definitive reentry intervals for ground and aerial applications of phorate granular products. Establishment of interim reentry intervals is based on the high acute toxicity properties of technical grade phorate.

8. The Agency is imposing revised and updated worker safety and protective clothing statements for EPs containing phorate. Refer to Section V for the wording of these statements.

Rationale: The Agency is concerned that exposure to phorate could present a health risk to agricultural workers due to the high acute toxicity of the technical grade of this pesticide. Revised and updated protective measures are being imposed to minimize this exposure.

9. The Agency will continue to restrict the use of products containing phorate.

Rationale: All granular formulations containing 5% phorate and greater were classified as restricted use pesticides under the 1984 Standard based upon a very high acute toxicity to humans and avian species. In addition, all granular formulations containing less than 5% phorate were classified restricted use pesticides pending receipt and evaluation of data. Registrants of products containing less than 5% phorate chose to restrict their products, rather than to submit data. The Agency will continue to restrict the use of all products containing phorate, having determined that phorate meets the risk criteria of 40 CFR 152.170 due to acute oral and dermal toxicity and bird toxicity.

10. The Agency is deferring requirement for a groundwater monitoring study, pending receipt and evaluation of a terrestrial field dissipation study and other required environmental fate studies.

Rationale: In the 1984 Standard, the Agency determined that phorate had some potential to leach through soil and contaminate groundwater, particularly where soils were sandy and aquifers shallow. Simulation of the leaching potential of phorate using computer modeling predicted some mobility in sandy soils, but none in loam soils under typical phorate use conditions.

Based on recently submitted data, phorate does not appear to be a potential leacher. However, its sulfone and sulfoxide degradates show greater persistence and mobility, and therefore may have a greater leaching potential. A terrestrial field dissipation study is required to be conducted in Long Island, New York. Depending on the results of this and other required environmental fate studies, the need for a groundwater monitoring study will be determined.

11. The Agency will revise commodity definitions for certain raw agricultural commodities listed in 40 CFR 180.206.

Rationale: Certain listings in 40 CFR 180.206 are not appropriate and will be corrected by the Agency:

a. The tolerance listing for wheat (green fodder) will be revised to read "wheat fodder". This is the appropriate commodity definition.

b. The designation "(N)" for negligible residues listed with the tolerances for milk, and meat, fat, and meat byproducts of cattle, goats, hogs, horse, poultry, and sheep and in eggs will be deleted. The Agency no longer sets "negligible" residue tolerances.

12. The Agency will revoke tolerances associated with the commodities alfalfa (fresh), alfalfa (hay), lettuce, rice, grass (bermuda straw), and tomatoes.

Rationale: These crops no longer have any federally registered uses. Therefore, the Agency intends to revoke the tolerances for these commodities.

13. The Agency intends to propose tolerances for corn fodder, bean hay, wheat hay and cotton forage.

Rationale: The Agency has determined that (1) 0.5 ppm is an appropriate tolerance level for bean hay and corn fodder, (2) 0.2 ppm is an appropriate tolerance level for cotton forage and (3) 1.5 ppm is an appropriate tolerance level for wheat hay. The Agency intends to propose these tolerance levels, unless the registrant submits labeling containing restrictions against the feeding of corn fodder, bean hay, wheat hay and cotton forage to livestock. The registrant must inform the Agency within 90 days of receipt of the Standard of what he intends to do.

14. For the crops sugarcane and cotton forage, the registrant is given the choice of developing and submitting data in support of tolerances, or of adding label restrictions against the feeding and grazing of treated crops to livestock. Each registrant must inform the Agency within 90 days as to whether he will propose tolerances or adopt the grazing/feeding restrictions. If he selects the label restrictions, labeling submitted at the 9 month deadline must include the grazing/feeding prohibitions. Refer to Section V for acceptable wording of a grazing/feeding restriction cotton forage and sugarcane.

Rationale: These raw agricultural commodities are used as feed and forage for livestock and tolerances are required. A label restriction prohibiting grazing/feeding will preclude residues in meat and milk.

15. A comparison has been made between the U.S. tolerances and Coded MRLs. Although there are some inconsistence between them, the Agency cannot revise the U.S. tolerances.

Rationale: Codex MRL's have been proposed on potatoes, sugar beets, sugar beet leaves and tops, and peanut hay at levels lower than the U.S. tolerances for these commodities. The available data indicate that, following registered use, the combined residue of phorate and its cholinesterase-inhibiting metabolites may exceed the proposed Coded MRL tolerances. Therefore, the U.S. tolerance cannot be decreased to achieve compatibility with the pending Coded MRL's.

Other comparisons between the U.S. tolerances and Codex MRL's include the following:

a. Codex MRL's have been proposed for beans, wheat grain, cottonseed, meat and egg, and poultry tissue and eggs. These levels are identical to that of the U.S. tolerance. The Codex MRL proposed for milk is higher than the U.S. tolerance.

b. No Codex MRL's have been established for bean vines, corn, sorghum grain, sorghum fodder, corn forage, wheat straw, and sugarcane (U.S. tolerances exist for these). Therefore, no questions of compatibility exist with respect to the MRL.

c. A Codex MRL has been proposed for dry soya beans. There is no U.S. tolerance for this commodity.

16. The Agency has identified certain data that will receive priority review when submitted to the Agency.

Rationale: Certain data are essential to the Agency's assessment of this pesticide and its uses and/or may trigger the need for further studies which should be initiated as soon as possible. The following studies have been identified to receive priority review as soon as they are received by the Agency:

Section 158.340 Toxicology

85-1	General Metabolism
-	Special Testing for Eye Effects
-	Short-term Mouse Study

Sections 158.290, 158.140 and 158.440 Environmental Fate

161-2,-3	Photodegradation
162-1,-2	Aerobic and Anaerobic Soil Metabolism
163-2	Lab Volatility

164-1	Soil Dissipation
165-1	Confined Rotational Crops
165-4	Fish Accumulation
132-1	Foliar and Soil Dissipation

Section 158.490 Wildlife and Aquatic Organisms

71-4	Avian Reproduction
72-3	Estuarine and Marine Organisms Testing using a TEP
72-4	Fish Early Life Stage and Invertebrate Life Cycle (Freshwater Fish)
72-4	Fish Early Life Stage and Invertebrate Life Cycle (Freshwater Invertebrates)
72-4	Fish Early Life Stage and Invertebrate Life Cycle (Estuarine Fish)
72-4	Fish Early Life Stage and Invertebrate Life Cycle (Estuarine Invertebrates)
72-7	Field Testing With Aquatic Organisms

Section 158.240 Residue Chemistry

Residue Analytical Methods
Poultry Metabolism Studies
Storage Stability Studies
Residue Data
Cooking and Processing Studies

17. While data gaps are being filled, currently registered products containing phorate may be sold, distributed, formulated, and used, subject to the terms and conditions specified in this Standard. However, significant new uses will not be registered. Registrants must provide or agree to develop additional data, as specified in the Data Appendices, in order to maintain existing registrations.

Rationale: Even when authorized under FIFRA sections 3(c)(2)(B) and 3(c)(7) the Agency may elect not to cancel or withhold registration even though data are missing or are inadequate. Issuance of this Standard provides a mechanism for identifying data needs. These data will be reviewed and evaluated, after which the Agency will determine if additional regulatory actions are necessary. The Agency has elected not to consider registration of any significant new food uses while data gaps are being filled and data evaluated.

V. REQUIRED LABELING STATEMENTS AND COMPLIANCE DATES

All products must bear appropriate labeling as specified in 40 CFR 156.10 and below.

Pesticide products containing this pesticide as an active ingredient may not be released for shipment by the registrant after January 31, 1990 unless the product bears amended labeling that complies with the requirements of FIFRA, as set out in this Registration Standard.

Pesticide products containing this pesticide as an active ingredient may not be distributed, sold, offered for sale, held for sale, shipped, delivered for shipment, or received (and having been so received) delivered or offered to be delivered by any person after January 31, 1991 unless that product bears amended labeling that complies with the requirements of this Standard.

A. MANUFACTURING USE PRODUCTS

1. The ingredient statement for MPs must declare the active ingredient as:

Phorate: O,O-diethyl S-[(ethylthio)
methyl] phosphorodithioate

2. Labels for MPs must bear the following identifying phrase directly beneath the product name:

"An insecticide for formulating use only."

3. In the directions for use, the following statement must appear:

"Formulators using this product are responsible for obtaining EPA registration of their formulated product."

4. In the directions for use, the following statement regarding acceptable use patterns must appear:

"For formulation into end-use insecticide products intended only for (list acceptable sites)."[8]

5. If detailed instructions for formulating are not provided on the label, the following statement must appear:

"Refer to attached Technical Bulletin for formulating and other information."

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[8] The Use Index (EPA Compendium of Acceptable Uses) (for availability see Section I) lists all federally-registered uses of phorate, as well as approved maximum application rates and frequencies. No use may be included on the label where the registrant fails to agree to comply with the data requirements for that use pattern.

6. The following statements are required to appear under the "Environmental Hazards" heading:

" This pesticide is extremely toxic to fish and wildlife. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or public waters unless this product is specifically identified and addressed in a NPDES Permit. Do not discharge effluent containing this product to sewer systems without previously notifying the sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA."

B. END USE PRODUCTS

1. The ingredient statement for EPs must declare the active ingredient as:

Phorate: O,O-diethyl S-[(ethylthio) methyl] phosphorodithioate

2. All EPs must bear the following restricted-use classification statement:

"RESTRICTED USE CLASSIFICATION
Due to acute oral and dermal toxicity and avian hazards

For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's Certification."

3. All EPs must bear the following environmental hazards statement:

"This pesticide is extremely toxic to fish and wildlife. Birds feeding in treated areas may be killed. Do not apply directly to water or wetlands (swamps, bogs, marshes, and pot-holes). Drift and runoff may be hazardous to aquatic organisms in neighboring areas. Collect or incorporate granules that are spilled during loading or are visible on soil surface in turn areas. Do not contaminate water when disposing of equipment washwaters."

4. All EPs (other than the granular formulations between 5 and 10%) must bear the following protective clothing statements and work safety rules:

PERSONAL PROTECTIVE EQUIPMENT

WEAR THE FOLLOWING PROTECTIVE CLOTHING DURING LOADING, APPLICATION, EQUIPMENT REPAIR/CLEANING, AND DISPOSAL OF THE

PESTICIDE. A protective suit of one or two pieces covering all parts of the body except head, hands, and feet; chemical resistant gloves; chemical resistant shoes, shoe covering, or boots.

Unless a chemical resistant protective suit is otherwise required, mixers/loaders must wear a chemical resistant apron and goggles or a face shield.

IF APPLICATION IS PERFORMED USING AN ENCLOSED CAB OR COCKPIT, THE FOLLOWING PROTECTIVE CLOTHING AND EQUIPMENT MAY BE WORN AS AN ALTERNATE: Long-sleeved shirt and long-legged pants; shoes and socks. Chemical resistant gloves must be available in the cab or cockpit and must be worn when exiting. This clothing is inadequate to protect you during equipment repair or cleaning, reentry, or pesticide disposal work. Do not allow contaminated clothing to come in contact with the insides of the cab.

IMPORTANT! If pesticide comes in contact with skin, wash off with soap and water. Always wash hands, face, and arms with soap and water before smoking, eating, drinking, or using the toilet.

AFTER WORK: Before removing gloves, wash them with soap and water. Take off all work clothes and shoes. Shower using soap and water. Wear clean clothes. Do not reuse contaminated clothing. Personal clothing worn during work must be laundered separately from household articles. Store protective clothing separately from personal clothing. Clean or launder protective clothing after each use. Clothing and protection equipment heavily contaminated must be destroyed according to state and local regulations. HEAVILY CONTAMINATED CLOTHING CANNOT BE ADEQUATELY DECONTAMINATED.

DURING AERIAL APPLICATION, HUMAN FLAGGERS ARE PROHIBITED UNLESS IN A TOTALLY ENCLOSED VEHICLE.

WORK SAFETY RULES

REPEATED EXPOSURES TO CHOLINESTERASE INHIBITORS SUCH AS ARE CONTAINED IN THIS PRODUCT MAY, WITHOUT WARNING, CAUSE PROLONGED SUSCEPTIBILITY TO VERY SMALL DOSES OF ANY CHOLINESTERASE INHIBITOR.

Persons working with this product should have frequent blood tests of their cholinesterase levels. If the cholinesterase level falls below a critical point, no further exposure should be allowed until it has been determined by means of blood tests that the cholinesterase level has returned to normal. Before using this product consult the National Pesticide Telecommunications Network for recommendations regarding such blood tests, poisoning management, emergency treatment, and other information regarding the toxicity of phorate. The toll free number for the National Pesticide Telecommunication Network is 1-800-858-7378.

If handled indoors provide mechanical exhaust ventilation.

Keep all unprotected persons, children, livestock, and pets away from treated areas or where there is danger of drift.

Do not rub eyes or mouth with hands. If you feel sick in any way, STOP work and get help right away, See First Aid (Practical Treatment) section.

5. All EPs (excluding the granular formulations between 5 and 10%) must bear the following protective clothing statements and work safety rules:

PERSONAL PROTECTIVE EQUIPMENT

WEAR THE FOLLOWING PROTECTIVE CLOTHING DURING LOADING, APPLICATION, EQUIPMENT REPAIR/CLEANING, AND DISPOSAL OF THE PESTICIDE. A protective suit of one or two pieces covering all parts of the body except head, hands, and feet; chemical resistant gloves; chemical resistant shoes, shoe covering, or boots. Wear goggles and a pesticide respirator approved by NIOSH or MSHA.

Unless a chemical resistant protective suit is otherwise required, mixers/loaders must wear a chemical resistant apron and goggles or a face shield.

The respirator need not be worn during equipment repair and cleaning and during early reentry after dust has settled.

IF APPLICATION IS PERFORMED USING AN ENCLOSED CAB OR COCKPIT, THE FOLLOWING PROTECTIVE CLOTHING AND EQUIPMENT MAY BE WORN AS AN ALTERNATE: Long-sleeved shirt and long-legged pants; shoes and socks. Chemical resistant gloves must be available in the cab or cockpit and must be worn when exiting. This clothing is inadequate to protect you during equipment repair or cleaning, reentry, or pesticide disposal work. Do not allow contaminated clothing to come in contact with the insides of the cab.

IMPORTANT! If pesticide comes in contact with skin, wash off with soap and water. Always wash hands, face, and arms with soap and water before smoking, eating, drinking, or using the toilet.

AFTER WORK: Before removing gloves, wash them with soap and water. Take off all work clothes and shoes. Shower using soap and water. Wear clean clothes. Do not reuse contaminated clothing. Personal clothing worn during work must be laundered separately from household articles. Store protective clothing separately from personal clothing. Clean or launder protective clothing after each use. Respirators must be cleaned and filters replaced according to instructions included with the respirator. Clothing and protection equipment heavily contaminated must be destroyed according to state and local regulations. HEAVILY CONTAMINATED CLOTHING CANNOT BE ADEQUATELY DECONTAMINATED.

DURING AERIAL APPLICATION, HUMAN FLAGGERS ARE PROHIBITED UNLESS IN A TOTALLY ENCLOSED VEHICLE.

WORK SAFETY RULES

REPEATED EXPOSURES TO CHOLINESTERASE INHIBITORS SUCH AS ARE CONTAINED IN THIS PRODUCT MAY, WITHOUT WARNING, CAUSE PROLONGED SUSCEPTIBILITY TO VERY SMALL DOSES OF ANY CHOLINESTERASE INHIBITOR.

Persons working with this product should have frequent blood tests of their cholinesterase levels. If the cholinesterase level falls below a critical point, no further exposure should be allowed until it has been determined by means of blood tests that the cholinesterase level has returned to normal. Before using this product consult the National Pesticide Telecommunications Network for recommendations regarding such blood tests, poisoning management, emergency treatment, and other information regarding the toxicity of phorate. The toll free number for the National Pesticide Telecommunication Network is 1-800-858-7378.

If handled indoors provide mechanical exhaust ventilation.

Keep all unprotected persons, children, livestock, and pets away from treated areas or where there is danger of drift.

Do not rub eyes or mouth with hands. If you feel sick in any way, STOP work and get help right away, See First Aid (Practical Treatment) section.

6. All EPs must bear the following reentry statements:

REENTRY

After dusts have settled, do not enter or allow entry into the treated area until the 48 hour reentry interval has expired, unless the person entering the treated area is wearing the personal protective equipment listed below for early reentry.

For early reentry into treated areas wear a protective suit of one or two pieces covering all parts of the body except head, hands, and feet; chemical-resistant gloves and chemical resistant shoes, shoe coverings, or boots.

7. All EPs allowing for use on peanuts must bear the following grazing and feeding restrictions:

"Do not graze or feed treated hay or forage to livestock."

8. All EPs allowing for use on cotton forage must bear the following restriction (in the absence of supporting residue chemistry data):

"Do not feed treated hay or forage to livestock."

9. All EPs allowing for use on sugarcane must bear the following restriction (in the absence of supporting residue chemistry data):

"Do not graze or feed treated hay or forage to livestock."

VI. PRODUCTS SUBJECT TO THIS STANDARD

All products containing one or more of the pesticides identified in Section II.A. are subject to certain requirements for data submittal or changes in composition, labeling or packaging of the product. The applicable requirements depend on whether the product is a manufacturing or end use product and whether the pesticide is the sole active ingredient or one of multiple active ingredients.

Products are subject to this Registration Standard as follows:

A. Manufacturing use products containing this pesticide as the sole active ingredient are subject to:

1. The restrictions (if any) upon use, composition, or packaging listed in Section IV, if they pertain to the manufacturing use product.

2. The data requirements listed in Tables A and B[9].

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[9] Data requirements are listed in the three Tables in Appendix I of this Registration Standard. The Guide to Tables in that Appendix explains how to read the Tables.

Table A lists generic data requirements applicable to all products containing the pesticide subject to this Registration

3. The labeling requirements specified for manufacturing use products in Section IV.

4. Administrative requirements (application forms, Confidential Statement of Formula, data compensation provisions) associated with reregistration.

B. Manufacturing use products containing this pesticide as one of multiple active ingredients are subject to:

1. The data requirements listed in Table A.

2. The labeling requirements specified for manufacturing use products in Section IV.

C. End use products containing this pesticide as the sole active ingredient are subject to:

1. The restrictions (if any) upon use, composition, or packaging listed in Section IV if they pertain to the end use product.

2. If eligible for the generic data exemption[10], the

Standard. Table B lists product-Specific data applicable to manufacturing-use products. The data in Tables A and B need not be submitted by an end-use producer who is eligible for the generic data exemption for that active ingredient.

Table C lists product-specific data applicable to end-use products. The Agency has decided that, in most cases, it will not require the submittal of product-specific data for end-use products at this time. Therefore, most Registration Standards do not contain a Table C.

[10] If you purchase from another producer and use as the source of your active ingredient only EPA-registered products, you are eligible for the generic data exemption for generic data concerning that active ingredient (Table A) and product-specific data for the registered manufacturing use product you purchase (Table B).

Two circumstances nullify this exemption:

1) If you change sources of active ingredient to an unregistered product, formulate your own active ingredient, or acquire your active ingredient from a firm with ownership in common with yours, you individually lose the exemption and become subject to the data requirements in Table A.

data requirements listed in Table C.

3. If not eligible for the generic data exemption, the data requirements listed in Table A and the data requirements listed in Table C.

4. The labeling requirements specified for end use products in Section IV.

D. End use products containing this pesticide as one of multiple active ingredients are subject to:

1. If not eligible for the generic data exemption, the data requirements listed in Tables A and C.

2. If eligible for the generic data exemption, the data requirements listed in Table C.

3. The labeling requirements specified for end use products in Section IV.

VI. REQUIREMENT FOR SUBMISSION OF GENERIC DATA

This portion of the Registration Standard is a notice issued under the authority of FIFRA sec. 3(c)(2)(B). It refers to the data listed in Table A, which are required to be submitted by registrants to maintain in effect the regis-tration of products containing this active ingredient.[11]

A. What are generic data?

Generic data pertain to the properties or effects of a particular active ingredient. Such data are relevant to an evaluation of all products containing that active ingredient regardless of whether the product contains other ingredients (unless the product bears labeling that would make the data requirement inapplicable).

Generic data may also be data on a "typical formulation" of a product. "Typical formulation" testing is often required for ecological effects studies and applies to all products having that formulation type. These are classed as generic data, and

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2) If no producer subject to the generic data requirements in Table A agrees to submit the required data, all end-use producers lose the exemption, and become subject to the data requirements in Table A.

[11] Registrations granted after issuance of this Standard will be conditioned upon submittal or citation of the data listed in this Registration Standard.

are contained in Table A.

B. Who must submit generic data?

All current registrants are responsible for submitting generic data in response to a data request under FIFRA sec. 3(c)(2)(B) (DCI Notice). EPA has decided, however, not to require a registrant who qualifies for the formulator's exemption (FIFRA sec. 3(c)(2)(D) and 40 CFR 152.85) to submit generic data in response to a DCI notice if the registrant who supplies the active ingredient in his product is complying with the data request.

If you are granted a generic data exemption, you rely on the efforts of other persons to provide the Agency with the required data. If the registrants who have committed to generate and submit the required data fail to take appropriate steps to meet the requirements or are no longer in compliance with this data requirements notice, the Agency will consider that both they and you are not in compliance and will normally initiate proceedings to suspend the registrations of both your product(s) and their product(s) unless you commit to submit and submit the required data in the specified timeframe. In such cases, the Agency generally will not grant a time extension for submitting the data.

If you are not now eligible for a generic data exemption, you may qualify for one if you change your source of supply to a registered source that does not share ownership in common with your firm. If you choose to change sources of supply, the Confidential Statement of Formula must identify the new source(s) and you must submit a Generic Data Exemption Statement.

If you apply for a new registration for products containing this active ingredient after the issuance of this Registration Standard, you will be required to submit or cite generic data relevant to the uses of your product if, at the time the application is submitted, the data have been submitted to the Agency by current registrants. If the required data have not yet been submitted, any new registration will be conditioned upon the new registrant's submittal or citation of the required data not later than the date upon which current registrants of similar products are required to provide such data. See FIFRA sec. 3(c)(7)(A). If you thereafter fail to comply with the condition of that registration to provide data, the registration may be cancelled (FIFRA sec. 6(e)).

C. What generic data must be submitted?

You may determine which generic data you must submit by consulting Table A. That table lists the generic data needed to evaluate current uses of all products containing this active ingredient, the uses for which such data are required, and the dates by which the data must be submitted to the Agency.

D. How to comply with DCI requirements.

Within 90 days of your receipt of this Registration Standard, you must submit to EPA a completed copy of the form entitled "FIFRA Section 3(c)(2)(B) Summary Sheet" (EPA Form 8580-1, enclosed) for each of your products. On that form you must state which of the following six methods you will use to comply with the DCI requirements:

1. You will submit the data yourself.

2. You have entered into an agreement with one or more registrants to jointly develop (or share in the cost of developing) the data, but will not be submitting the data yourself. If you use this method, you must state who will submit the data on which you will rely. You must also provide EPA with documentary evidence that an agreement has been formed which allows you to rely upon the data to be submitted. Such evidence may be: (1) your letter offering to join in an agreement and the other registrant's acceptance of your offer, (2) a written statement by the parties that an agreement exists, or (3) a written statement by the person who will be submitting the data that you may rely upon its submittal. The Agency will also require adequate assurance that the person whom you state will provide the data is taking appropriate steps to secure it. The agreement to produce the data need not specify all of the terms of the final arrangement between the parties or a mechanism to resolve the terms.

If you and other registrants together are generating or submitting requested data as a task force or consortium, a representative of the group should request a Joint Data Submitter Number, as part of your 90-day response. The request must include the following information:

a. A list of the members of the consortium;
b. The name and address of the designated representative of the consortium, with whom EPA will correspond concerning the data;
c. Identity of the Registration Standard containing the data requirement;
d. A list of the products affected (from all members of the consortium); and
e. Identification of the specific data that the consortium will be generating or submitting.

The Agency will assign a number to the consortium, which should be used on all data submittals by the consortium.

3. You have attempted to enter into an agreement to jointly develop data, but no other registrant has accepted your offer. You request that EPA not suspend your registration for non-compliance with the DCI. EPA has determined that, as a general policy, it will not suspend the registration of a product when the registrant has in good faith sought and continues to seek to enter into a data development/cost sharing program, but the other registrants developing the data have refused to accept its offer. [If your offer is accepted, you may qualify for Option 2 above by entering into an agreement to supply the data.]

In order to qualify for this method, you must:

1. File with EPA a completed "Certification of Attempt to Enter into an Agreement with other Registrants for Develop-ment of Data" (EPA Form 8580-6, enclosed).

2. Provide us with a copy of your offer to the other registrant and proof of the other registrant's receipt of your offer (such as a certified mail receipt). Your offer must, at a minimum, contain the following language or its equivalent:

> [Your company name] offers to share in the burden of producing the data required pursuant to FIFRA sec. 3(c)(2)(B) in the [name of active ingredient] Registration Standard upon terms to be agreed or failing agreement to be bound by binding arbitration as provided by FIFRA sec. 3(c)(2)(B)(iii).

The remainder of your offer may not in any way attempt to limit this commitment. If the other registrant to whom your offer is made does not accept your offer, and if the other registrant informs us on a DCI Summary Sheet that he will develop and submit the data required under the DCI, then you may qualify for this option. In order for you to avoid suspension under this method, you may not later withdraw or limit your offer to share in the burden of developing the data.

In addition, the other registrant must fulfill its commitment to develop and submit the data as required by this Notice in a timely manner. If the other registrant fails to develop the data or for some other reason would be subject to suspension, your registration as well as that of the other registrant will normally be subject to initiation of suspension proceedings, unless you commit to submit and submit the required data in the specified timeframe. In such cases, the Agency generally will not grant a time extension for submitting the data.

4. You request a waiver of the data requirement. If you believe that a data requirement does not (or should not) apply to your product or its uses, you must provide EPA with a statement

of the reasons why you believe this is so. Your statement must address the specific composition or use factors that lead you to believe that a requirement does not apply. Since the Agency has carefully considered the composition and uses of pesticide products in determining that a data require-ment applies, EPA does not anticipate that many waivers will be granted. A request for waiver does not extend the time-frames for developing required data, and if your waiver request is denied, your registration may be suspended if you fail to submit the data. The Agency will respond in writing to your request for a waiver.

5. You request that EPA amend your registration by deleting the uses for which the data are needed. You are not required to submit data for uses which are no longer on your label.

6. You request voluntary cancellation of the registration of your product(s) for which the data are needed.

E. Registrant Requests Regarding Data Requirements and Agency Responses

All requests for modification of data requirements (inapplicability, waiver), approval of protocols or protocol changes, or time extensions must be submitted in writing. The original requirement remains in effect unless the Agency has notified you in writing that it has agreed to a change in the requirement. While being considered by the Agency, such requests for changes in the requirements do not alter the original requirements or extend the time allowed for meeting the requirement.

F. Test Protocols and Standards

All studies required under this Notice must be conducted in accordance with test standards outlined in the Pesticide Assessment Guidelines, unless other protocol or standards are approved for use by the Agency in writing. All testing must be conducted in accordance with applicable Good Laboratory Practices regulations in 40 CFR Part 160.

The Pesticide Assessment Guidelines, which are referenced in the Data Tables, are available from the National Technical Information Service (NTIS), Attn: Order Desk, 5285 Port Royal Road, Springfield, VA 22161 (tel: 703-487-4650).

Protocols approved by the Organization for Economic Cooperation and Development (OECD) are also acceptable if the OECD-recommended test standards conform to those specified in the Pesticide Data Requirements regulation (Part 158.70). Please note, however, that certain OECD standards (such as test duration, selection of test species, and degradate identification which are environmental fate requirements) are less restrictive than those in the EPA Assessment Guidelines listed above. When using the OECD protocols, they should be be modified as appropriate so that the data generated by the study will satisfy the requirements of Part 158. Normally, the Agency will not extend deadlines for complying with data requirements when the studies were not conducted in accord with acceptable standards. The OECD protocols are available from OECD, 1750 Pennsylvania Avenue, N.W., Washington, D.C. 20006.

G. Procedures for requesting a change in test protocol.

If you will generate the required data and plan to use test procedures which deviate from EPA's Pesticide Assessment Guidelines or the Reports of Expert Groups to the Chemicals Group, Organization for Economic Cooperation and Development (OECD) Chemicals Testing Programme, you must submit for EPA approval the protocols you propose to use.

You should submit your protocols before beginning testing, because the Agency will not ordinarily accept as sufficient studies using unapproved protocols. A request for protocol approval will not extend the timeframe for submittal of the data, nor will extensions generally be given to conduct studies due to submittal of inappropriate protocols. The Agency will respond in writing to your request for protocol approval or change.

H. Procedures for requesting extensions of time.

If you think that you will need more time to generate the data than is allowed by EPA's schedule, you may submit a request for an extension of time.

EPA will view failure to request an extension before the data submittal response deadline as a waiver of any future claim that there was insufficient time to submit the data. While EPA considers your request, you must strive to meet the deadline for submitting the data.

The extension request should state the reasons why you believe that an extension is necessary and the steps you have taken to meet the testing deadline. Time extensions normally will not be granted due to problems with laboratory capacity or adequacy of funding, since the Agency believes that with proper planning these can be overcome. The Agency will respond in writing to any requests for extension of time.

I. Data Format and Reporting Requirements

All data submitted in response to this Notice must comply with EPA requirements regarding the reporting of data, including the manner of reporting, the completeness of results, and the adequacy of any required supporting (or raw) data, including, but not limited to, requirements referenced or included in this Notice or contained in PR Notice 86-5 (issued July 29, 1986). All studies must be submitted in the form of a final report; a preliminary report will not be considered to fulfill the submittal requirement.

J. Existing stocks provision upon suspension or cancellation.

The Agency has determined that if a registration is suspended for failure to respond to a DCI request under FIFRA sec. 3(c)(2)(B), an existing stocks provision for the registrant is not consistent with the Act. Accordingly, the Agency does not anticipate granting permission to sell or distribute existing stocks of suspended product except in rare circumstances. If you believe that your product will be suspended or cancelled and that an existing stocks provision should be granted, you have the burden of clearly demonstrating to EPA that granting such permission would be consistent with the Act. The following information must be included in any request for an existing stocks provision:

1. Explanation of why an existing stocks provision is necessary, including a statement of the quantity of existing stocks and your estimate of the time required for their sale or distribution; and

2. Demonstration that such a provision would be consistent with the provisions of FIFRA.

VII. REQUIREMENT FOR SUBMISSION OF PRODUCT-SPECIFIC DATA

Under its DCI authority, EPA has determined that certain product-specific data are required to maintain your registrations in effect. Product-specific data are derived from testing using a specific formulated product, and, unlike generic data, generally support only the registration of that product. All such data must be submitted by the dates specified in this Registration Standard.

If you have a manufacturing use product, these data are listed in Table B. If you have an end use product, the data are listed in Table C. As noted earlier, the Agency has decided that it will not routinely require product-specific data for end use products at this time. Therefore, Table C may not be contained in this Registration Standard; if there is no Table C, you are not required to submit the data at this time.

In order to comply with the product specific data requirements, you must follow the same procedures as for generic data. See Section VI.D through J. You should note, however, that product chemistry data are required for every product, and the only acceptable responses are options VI.D.1. (submit data) or

VI.D.6.(cancellation of registration).

Failure to comply with the product-specific data requirements for your products will result in suspension of the product's registration.

VIII. REQUIREMENT FOR SUBMITTAL OF REVISED LABELING

FIFRA requires each product to be labeled with accurate, complete and sufficient instructions and precautions, reflecting the Agency's assessment of the data supporting the product and its uses. General labeling requirements are set out in 40 CFR 156.10 (see Appendix II - LABELING and SUMMARY). In addition, labeling language specific to products containing this pesticide is specified in Section IV.D of this Registra-tion Standard. Responses to this Registration Standard must include draft labeling for Agency review.

Labeling must be either typewritten text on 8-1/2 x 11 inch paper or a mockup of the labeling suitable for storage in 8-1/2 x 11 files. Draft labeling must indicate the intended colors of the final label, clear indication of the front panel of the label, and the intended type sizes of the text.

If you fail to submit revised labeling as required, which complies with 40 CFR 156.10 and the specific instructions in Section IV.D., EPA may seek to cancel the registration of your product under FIFRA sec. 6.

IX. INSTRUCTIONS FOR SUBMITTAL

All submittals in response to this Registration Standard must be sent to the following address:

Office of Pesticide Programs
OPP Mailroom (TS-767C)
Environmental Protection Agency
401 M St., SW
Washington, D.C. 20460

Attn: Phorate Registration Standard

A. Manufacturing Use Products (MUPs) containing the subject pesticide as sole active ingredient.

1. Within 90 days from receipt of this document, you must submit for each product subject to this Registration Standard:

a. Generic Data Exemption Statement (EPA Form 8580-3), if applicable, or the "FIFRA Section 3(c)(2)(B) Summary Sheet" (EPA Form 8580-1), with appropriate attachments.

b. Confidential Statement of Formula (EPA Form 8570-4).

c. Evidence of compliance with data compensation requirements of FIFRA sec. 3(c)(1)(D). Refer to 40 CFR 152.80-152.99.

2. Within 9 months from receipt of this document you must submit:

a. Application for Pesticide Registration (EPA Form 8570-1).

b. Two copies of any required product-specific data (See Table B).

c. Three copies of draft labeling, including the container label and any associated supplemental labeling.

d. Product Specific Data Report (EPA Form 8580-4).

3. Within the times set forth in Table A, you must submit all generic data, unless you are eligible for the generic data exemption. If for any reason any test is delayed or aborted so that the schedule cannot be met, immediately notify the Agency of the problem, the reasons for the problem, and your proposed course of action.

B. Manufacturing Use Products containing the subject pesticide in combination with other active ingredients.

1. Within 90 days from receipt of this document, you must submit:

a. Generic Data Exemption Statement (EPA Form 8580-3), if applicable, or the FIFRA sec. 3(c)(2)(B) Summary Sheet, with appropriate attachments (EPA Form 8580-1).

b. Confidential Statement of Formula (EPA Form 8570-4)

2. Within 9 months of receipt of this document, you must submit:

Three copies of draft labeling, including the container label and any associated supplemental labeling.

3. Within the time frames set forth in Table A, you must submit all generic data, unless you are eligible for the generic data exemption. If for any reason any test is delayed or aborted so that the schedule cannot be met, immediately notify the Agency of the problem, the reasons for the problem, and your proposed course of action.

C. End Use Products containing the subject pesticide as sole active ingredient.

1. Within 90 days from receipt of this document, you must submit:

a. Generic data exemption Statement (EPA Form 8580-3), if applicable, or the FIFRA Section 3(c)(2)(B) Summary Sheet, with appropriate attachments (EPA Form 8580-1).

b. Confidential Statement of Formula (EPA Form 8570-4).

2. Within 9 months from receipt of this document you must submit:

a. Two copies of any product-specific data, if required by Table C.

b. Product Specific Data Report (EPA Form 8580-4), if Table C lists required product-specific data.

c. Three copies of draft labeling, including the container label and any associated supplemental labeling.

3. Within the times set forth in Table A, you must submit all generic data, unless you are eligible for the generic data exemption. If for any reason any test is delayed or aborted so that the schedule cannot be met, immediately notify the Agency of the problem, the reasons for the problem, and your proposed course of action.

D. End Use Products containing the subject active ingredient as one of multiple active ingredients

1. Within 90 days from receipt of this document, you must submit:

a. Generic data exemption Statement (EPA Form 8580-3), if applicable, or the FIFRA Section 3(c)(2)(B) Summary Sheet, with appropriate attachments (EPA Form 8580-1).

b. Confidential Statement of Formula (EPA Form 8570-4).

2. Within 9 months from the receipt of this document, you must submit:

Three copies of draft labeling, including the container label and any associated supplemental labeling.

3. Within the times set forth in Table A, you must submit all generic data, unless you are eligible for the generic data

exemption. If for any reason any test is delayed or aborted so that the schedule cannot be met, immediately notify the Agency of the problem, the reasons for the problem, and your proposed course of action.

E. Intrastate Products

Applications for full Federal registration of intrastate products were required to be submitted no later than July 31, 1988. Unless an application for registration was submitted by that date, no product may be released for shipment by the producer after July 31, 1988.

I. DATA APPENDICES

GUIDE TO TABLES

Tables A, B, and C contain listings of data requirements for the pesticides covered by this Registration Standard.

Table A contains generic data requirements that apply to the pesticide in all products, including data requirements for which a "typical formulation" is the test substance.

Table B contains product-specific data requirements that apply only to a manufacturing use product.

Table C contains product-specific data requirements that apply only to an end use product.

The data tables are generally organized according to the following format:

1. Data Requirement (Column 1). The data requirements are listed in the order in which they appear in 40 CFR Part 158. The reference numbers accompanying each test refer to the test protocols set out in the Pesticide Assessment Guidelines, which are available from the National Technical Information Service, 5285 Prot Royal Road, Springfield, VA 22161.

2. Test Substance (Column 2). This column lists the composition of the test substance required to be used for the test, as follows:

TGAI = Technical grade of the active ingredient
PAI = Pure active ingredient
PAIRA = Pure Active ingredient, radio labeled
TEP = Typical end use formulation
MP = Manufacturing use product
EP = End use product

Any other test substances, such as metabolites, will be specifically named in Column 2 or in footnotes to the table.

3. Use pattern (Column 3). This column indicates the use patterns to which the data requirement applies. Use patterns are the same as those given in 40 CFR Part 158. The following letter designations are used for the given use patterns:

A = Terrestrial, food
B = Terrestrial, non-food
C = Aquatic, food
D = Aquatic, non-food
E = Greenhouse, food

F = Greenhouse, non-food
G = Forestry
H = Domestic outdoor
I = Indoor

Any other designations will be defined in a footnote to the table.

4. Does EPA have data? (Column 4). This column indicates one of three answers:

> YES - EPA has data in its files that completely satisfy this data requirement. These data may be cited by other registrants in accordance with data compensation requirements of Part 152, Subpart E.
>
> PARTIALLY - EPA has some data in its files, but such data do not fully satisfy the data requirement. In some cases, the Agency may possess data on one of two required species or may possess data on one test substance but not all. The term may also indicate that the data available to EPA are incomplete. In this case, when the data are clarified, or additional details of the testing submitted by the original data submitter, the data may be determined to be acceptable. If this is the case, a footnote to the table will usually say so.
>
> NO - EPA either possesses no data which are sufficient to fulfill the data requirement, or the data which EPA does possess are flawed scientifically in a manner that cannot be remedied by clarification or additional information.

5. Bibliographic citation (Column 5). If the Agency has acceptable data in its files, this column lists the identifying number of each study. This normally is the Master Record Identification (MRID) number, but may be a GS number if no MRID number has been assigned. Refer to the Bibliography Appendices for a complete citation of the study.

6. Must additional data be submitted? (Column 6). This column indicates whether the data must be submitted to the Agency. If column 3 indicates that the Agency already has data, this column will usually indicate NO. If column e indicates that the Agency has only partial data or no data, this column will usually indicate YES. In some cases, even though the Agency does not

have the data, EPA will not require its submission because of the unique characteristics of the chemical; because data on another chemical can be used to fulfill the data requirement; or because the data requirement has been waived or reserved. Any such unusual situations will be explained in a footnote to the table.

7. Timeframe for submission (Column 7). If column t requires that data be submitted, this column indicates when the data are to be submitted, based on the issuance date of the Registration Standard. The timeframes are those established either as a result of a previous Data Call-In letter, or standardized timeframes established by PR Notice 85-5 (August 22, 1985).

8. Footnotes (at the end of each table). Self-explanatory.

Table A
Generic Data Requirements for Phorate

Data Requirement	Test Substance	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe For Data Submission[1]
Part 158, Subpart C - Product Chemistry					
Product Identity and Composition					
61-2 - Description of Beginning Materials and Manufacturing Process	TGAI	Partially	00146524, 00155595	Yes[2]	9 Months
61-3 - Discussion of Formation of Impurities	TGAI	Partially	00146524, 00158941	Yes[3]	9 Months
Analysis and Certification of Product Ingredients					
62-1 - Preliminary Analysis of Product Samples	TGAI	Partially	00146524	Yes[4]	12 Months
Physical and Chemical Characteristics					
63-2 - Color	TGAI	Yes	00146524, 00149814	No	
63-3 - Physical State	TGAI	Yes	00146524, 00149814	No	
63-4 - Odor	TGAI	Yes	00146524, 00158941	No	
63-5 - Melting Point	TGAI	N/A		No[5]	
63-6 - Boiling Point	TGAI	Partially	00146524, 00149814	Yes[6]	9 Months

Table A
Generic Data Requirements for Phorate (cont'd)

Data Requirement	Test Substance	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe For Data Submission[1]
Part 158, Subpart C - Product Chemistry					
Physical and Chemical Characteristics (cont'd)					
63-7 - Density, Bulk Density, or Specific Gravity	TGAI	Yes	00146524, 00149814	No	
63-8 - Solubility	TGAI or PAI	Partially	00146524, 00158941	Yes[7]	9 Months
63-9 - Vapor Pressure	TGAI or PAI	Partially	00146524, 00149814	Yes[8]	9 Months
63-10 - Dissociation Constant	TGAI or PAI	N/A			
63-11 - Octanol/Water Partitioning Coefficient	PAI	Partially	00146524, 00149814	Yes[9]	9 Months
63-12 - pH	TGAI	Yes	00146524, 00158941	No	
63-13 - Stability	TGAI	Partially	00146524	Yes[10]	9 Months

Table A
Generic Data Requirements for Phorate (cont'd)

Part 158. Subpart C - Product Chemistry (cont'd)

1/Due dates refer to number of months following receipt of this Registration Standard, unless otherwise indicated.

2/Information must be submitted for the American Cyanamid 85% Ts (EPA Registration Nos. 241-213 and 241-212) and the 89.4% T (EPA Registration No. 2749-106) regarding the relative amounts of beginning materials and the order in which they are added, the equipment used to produce each intermediate and the final product, reaction conditions, the duration of each step of the process, and quality control measures. In addition, the name and address of the manufacturer, producer, or supplier of each beginning material used in the manufacture of each product must be provided for the Aceto product, as well as a statement regarding the nature of the process (batch or continuous), and flow chart with chemical equations of each intended chemical reaction.

3/For the 89.4% T (EPA Registration No. 2749-106), a detailed discussion of all impurities that are or may be present at ≥ 0.1%, based on knowledge of the beginning materials, chemical reactions (intended and side) in the manufacturing process, and any contamination during and after production must be submitted.

4/Five or more representative batches of the Aceto 89.4% T (EPA Registration No. 2749-106) must be analyzed for the amount of active ingredient and each impurity for which certified limits are required. Complete detailed descriptions of the analytical methods used for analysis of the Aceto 89.4% T and the Cyanamid 85% Ts (EPA Registration Nos. 241-213 and 241-212) along with validation data (accuracy and precision) must also be submitted.

5/Data not required because the technical product is mobile liquid at 20 to 25 ^{0}C.

6/The submitted data satisfy the requirements for the 89.4% T (EPA Registration No. 2749-106). The submitted data do do not satisfy these requirements for the 85% Ts (EPA Registration Nos. 241-213 and 241-212) because details of the methodology used were not provided. These data are required.

7/The submitted data satisfy the requirements for the 89.4% T (EPA Registration No. 2749-106). No data were submitted regarding solubility in polar (other than distilled water) and nonpolar solvents for the 85% Ts (EPA Registration No. 241-213 and 241-212). These data are required.

8/The submitted data do not satisfy the requirements for the 85% Ts (EPA Registration Nos. 241-213 and 241-212) because the methodology was not described. The submitted data do not satisfy these requirements for the 89.4% T (EPA Registration No. 2749-106) because the vapor pressure was not measured at 25 ^{0}C. In addition, the method used must be provided.

9/The submitted data do not satisfy the requirements for the 85% T (EPA Registration No. 241-213) because the temperature was not reported and the method was not provided. The submitted data do not satisfy these requirements for the 89.4% T (EPA Registration No. 2749-106) because a Kow value was not clearly reported and the method used was not provided. These data are required.

10/No quantitative data were submitted to satisfy the requirements for the 85% Ts (EPA Registration Nos. 241-213 and 241-212). No data regarding stability were submitted for the 89.4% T (EPA Registration No. 2749-106).

Table A
Generic Data Requirements for Phorate

Data Requirement	Test Substance	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe For Data 1/ Submission
Sec. 158.240 Residue Chemistry					
171-4 - Nature of the Residue (Metabolism) - Plants	PAIRA	Yes	00034557, 00092876, 00092877, 00153487	No	
171-4 - Nature of the Residue (Metabolism)	PAIRA and Plant Metabolites	Partially	00092877, 00156201	Yes[2,3/]	18 Months
171-4 - Residue Analytical Methods	TGAI and Metabolites	Partially	00033566, 00035323, 00035909, 00044747, 00052243, 00092848, 00092875, 00092878, 00092887, 00092889, 00092890, 00092891, 00092905, 00092911, 00092933, 00092940, 00092979, 00092988, 00160048, 00161575, 00161576, 40000601, 40197201, 40197202, 40197203, 40263401, 40586504, 40586505	Yes[4,5,6,7/]	15 Months
171-4 - Storage Stability	TEP and Metabolites	Partially	40386302, 40386303, 40386304, 40386305, 40386306	Yes[8,9/]	15 Months

Table A
Generic Data Requirements for Phorate (cont'd)

Data Requirement	Test Substance	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe For Data 1/ Submission
Sec 158.240 Residue Chemistry					
171-4 - Magnitude of the Residue in Plants[10]/					
Root and Tuber Vegetables					
- Potatoes (Processed)	TEP	Partially	00092887, 40174517, 40197204, 40197207	Yes[11,12]/	24 Months
- Sugar Beets	TEP	Partially	00092856, 00092875, 00092893, 00153487, 40174518	Yes[13]/	18 Months
Leaves of Root and Tuber Vegetables					
- Sugar Beet Tops	TEP	Partially	00092856, 00092875, 00092893, 40174518	Yes[14]/	18 Months
Legume Vegetables					
- Beans	TEP	Partially	40197206, 40174519	Yes[10,15]/	18 Months
- Soybeans	TEP	Yes	00092930, 40174522	No	
Foliage of Legume Vegetables					
- Bean Vines and Hay	TEP	Partially	40197206, 40174519	Yes[16,17]/	18 Months

Table A
Generic Data Requirements for Phorate (cont'd)

Data Requirement	Test Substance	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe For Data [1] Submission
Sec 158.240 Residue Chemistry					
171-4 - Magnitude of the Residue in Plants (cont'd)					
Cereal Grains					
- Corn, Field and Fresh	TEP	Partially	00092884, 00142921, 00158330, 00160047, 00161821, 40000602, 40174523	Yes[10,18,19,20]	18 Months
- Sorghum	TEP	Partially	00033562, 00034566, 00044614, 00052243, 00092914, 00092938, 00093008, 00094695, 40174520	Yes[10,21]	18 Months
- Processed Sorghum Products	TEP	No		Yes[22]	24 Months
- Wheat	TEP	Partially	00033560, 00092990, 00092926, 00014314, 00160048	Yes[5,10]	24 Months
- Processed Wheat Products	TEP	No		Yes[23]	24 Months
- Barley Grain	TEP	No		Yes[24]	18 Months
- Processed Barley Grain	TEP	No		Yes[25]	24 Months

Table A
Generic Data Requirements for Phorate (cont'd)

Data Requirement	Test Substance	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe For Data[1]/ Submission
Sec. 158.240 Residue Chemistry					
171-4 - Magnitude of the Residue in Plants (cont'd)					
Forage, Fodder, and Straw of Cereal Grains					
- Corn Forage and Fodder	TEP	Partially	00092884, 00142921, 00158330, 00160047, 40174514	Yes[26]/	18 Months
- Sorghum Forage and Fodder	TEP	Partially	00033562, 00034566, 00044614, 00052243, 00092914, 00092938, 00093008, 00094695, 40174520	Yes[27,28]/	18 Months
- Wheat Forage, Hay, and Straw	TEP	Partially	00033560, 00092990, 00092926, 00014314, 00160048, 40174516	Yes[29]/	18 Months
-Barley Forage, Hay and Straw	TEP	No		Yes[30]/	18 Months
Miscellaneous Commodities					
- Cottonseed	TEP	Partially	00092846, 00092848, 00092925, 40174521	Yes[31]/	18 Months
- Peanuts	TEP	Partially	00052383, 00092886, 00161575, 40174515, 40197209, 40386301, 40586501	Yes[32]/	18 Months

Table A
Generic Data Requirements for Phorate (cont'd)

Data Requirement	Test Substance	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe For Data Submission 1/
Sec. 158.240 Residue Chemistry					
- Sugarcane	TEP	Partially	00044751, 00161576	Yes10,33/	18 Months
- Sugarcane Bagasse	TEP	No		Yes34/	24 Months
- Hops	TEP	No		Yes35/	24 Months2/
171-4 - Magnitude of Residue in Meat/Milk/Poultry/Eggs	TGAI or Plant Metabolites	Partially	00092978	Yes36,37/	24 Months2/

Table A
Generic Data Requirements for Phorate (cont'd)

Sec. 158.240 Residue Chemistry (cont'd)

1/Due dates refer to the number of months following receipt of the Registration Standard, unless otherwise indicated.

2/Metabolism studies are required utilizing poultry. [These studies were not required in the 1984 Standard, but were required in a later review for an amended registration.] Animals must be dosed orally for a minimum of 3 days with [^{14}C]phorate at a level sufficient to make residue identification and quantification possible. Eggs must be collected twice a day during the dosing period, and hens must be sacrificed within 24 hours of the final dose. The distribution and identity of residues must be determined in eggs, liver, kidney, muscle, and fat. Samples from these studies must also be analyzed using enforcement methods to ascertain that tolerance enforcement methods are capable of adequately recovering all residues of toxicological concern.

3/Swine metabolism data are also required if the metabolism studies with ruminants and poultry reveal that the metabolism of phorate in these animals differs from that in rats.

4/An analytical method and appropriate supporting validation data must be submitted which permit individual identification and quantification of phorate and its oxidation products phorate sulfone, phorate sulfoxide, phorate oxygen analog sulfone, and phorate oxygen analog sulfoxide in or on plant and animal commodities. Validation data must support the stated limits of detection.

5/Validation data must be submitted on American Cyanamid Methods M-1637, M-1642, M-1672, M-1722, M-1724, M-1706, M-1725, M-1734, M-1752, and M-1780, and descriptions and validation data must be submitted for Methods M-1559 and M-1618. The validation data must reflect separate fortifications of phorate and its sulfoxide, sulfone, oxygen analog, oxygen analog sulfoxide, and oxygen analog sulfone for each commodity tested.

6/Residues of phorate and its sulfone, sulfoxide, oxygen analog sulfone, and oxygen analog sulfoxide metabolites occurring in or on plant commodities, meat, milk, poultry, and eggs must be subjected to analysis by PAM Vol. I method 242.2 (multiresidue protocol IV). Residues of the sulfone, sulfoxide, oxygen analog, and oxygen analog sulfoxide metabolites of phorate occurring in on raw agricultural commodities, meat, milk, poultry, and eggs must be subjected to analysis by PAM Vol. I methods 211.1/212.1/252 (multiresidue protocol I). Residues of the oxygen analog, oxygen analog sulfone, and oxygen analog sulfoxide metabolites of phorate occurring in or on plant commodities, meat, milk, poultry, and eggs must be subjected to analysis by PAM Vol. I method 232.4 (multiresidue protocol III). Residues of the oxygen analog sulfoxide and oxygen analog sulfone metabolites of phorate occurring in or on plant commodities, meat, milk, poultry, or eggs must be subjected to analysis by PAM Vol. I method 232.3 (multiresidue protocol II). Multiresidue protocols are published in PAM Vol. I, Appendix II and are available from the National Technical Information Service under Order No. PB 203734/AS.

7/The nature of the residues in poultry is not adequately understood. If the requested poultry metabolism studies reveal the presence of additional residues of toxicological concern in commodities, additional validated methods for data collection and tolerance enforcement may be required.

Table A
Generic Data Requirements for Phorate (cont'd)

Sec. 158.240 Residue Chemistry (cont'd)

8/All residue data required in this Standard must be accompanied by information specifying the storage intervals and conditions for samples analyzed. Data must also be submitted depicting the storage stability of the residues of concern under the same conditions and intervals specified. In laboratory tests using fortified samples, the pure active ingredient and pure metabolites (if necessary) must be used. However, if field weathered samples are used, the test substance must be a typical end-use product.

9/Data are required depicting the intervals and conditions of the storage of samples used to collect residue data for snap beans, (MRID Nos. 40174519 and 40197206), corn grain (MRID No. 00158330), sweet corn (MRID 00160047), corn forage (MRID Nos. 00160047 and 00158330), processed commodities of corn grain (MRID Nos. 40000602 and 40174523), wheat grain, forage, and straw (MRID No. 00160048), cottonseed and cottonseed forage (MRID No. 40174521), peanut nutmeats and hulls (MRID No. 00161575), cottonseed and cottonseed forage (MRID No. 40174521), peanut nutmeats and hulls (MRID No. 00161575), processed commodities of peanuts (MRID No. 00161575), and sugarcane (MRID No. 00161576).

10/In all cases where additional residue data are required if detectable (> 0.05 ppm) residues of phorate are observed, then analyses of those commodities using validated methodology which determines phorate and each of its metabolites separately are required.

11/Data are required depicting phorate residues of concern in chips, granules, and wet and dry peel from potatoes bearing measurable weathered residues. If residues concentrate in peel or granules, appropriate feed/food additive tolerances must be proposed.

12/Data are required depicting the phorate residues of concern in french fried potatoes, baked whole potatoes with peel, baked potato flesh, baked potato peel, boiled whole potatoes with peel, and boiled potato flesh prepared from potatoes bearing measurable weathered residues. All major degradation products accounted for and identified in the cooked samples.

13/Data are required depicting phorate, phorate sulfoxide, phorate sulfone, phorate oxygen analog, phorate oxygen analog sulfoxide, and phorate oxygen analog sulfone, each quantitated separately, in or on sugar beet roots harvested 30 days following postemergence soil application of a representative G formulation at 1.5 lb ai/A followed by foliar application of a G formulation at 1.5 lb ai/A. The use of aerial and ground equipment must be represented in separate tests. Alternatively, data depicting these residues in or on the samples bearing detectable combined residues reported in MRID No. 40174518 (Report No. C-2919) may satisfy these requirements. In addition, the registrants must amend all pertinent product labels to specify a number of foliar applications per season or a maximum seasonal application rate, which must be consistent with that reflected in the residue data used to support the tolerance.

14/Data are required depicting phorate, phorate sulfoxide, phorate sulfone, phorate oxygen analog, phorate oxygen analog sulfoxide, and phorate oxygen analog sulfone, each quantitated separately, in or on sugar beet tops harvested 30 days following postemergence soil application of a representative G formulation at 1.5 lb ai/A followed by foliar application of a G formulation at 1.5 lb/A. The use of aerial and ground equipment must be

Table A
Generic Data Requirements for Phorate (cont'd)

Sec. 158.240 Residue Chemistry (cont'd)

represented in separate tests. Alternatively, data depicting these residues in or on the samples bearing detectable combined residues reported in MRID No. 40174518 (Report No. C-2919) may satisfy these requirements. The registrants must amend all pertinent product labels to specify a number of foliar applications per season or a maximum seasonal application rate, which must be consistent with that reflected in the residue data used to support the tolerance.

15/Data are required depicting the combined residues of phorate in or on dry beans harvested following at-planting soil application of a representative G formulation at 2.1 lb ai/A. Although adequate data on succulent beans have been submitted, data on dry beans were submitted only from MI which does not adequately represent the Central U.S. and no data from the western states were submitted. Moreover, data from only two samples were reported. Agency interpretation of existing Guidelines regarding the volume of data required and geographic representation of test states has become stricter. Therefore, the data on dry beans do not fulfill Agency requirements.

16/Data are required depicting phorate, phorate sulfoxide, phorate sulfone, phorate oxygen analog, phorate oxygen analog sulfoxide, and phorate oxygen analog sulfone, each quantitated separately, in or on bean vines harvested 60 days following band soil application made at planting of a representative G formulation at 2.1 lb ai/A.

17/Since hay is a raw agricultural commodity of beans, a tolerance must be proposed for bean hay. The available data indicate that a tolerance of 0.5 ppm would be appropriate. Alternatively, the registrant may propose a restriction of the feeding of bean hay to livestock

18/Data are required depicting the combined residues of phorate in or on field corn harvested 90 days following a foliar application, using aerial equipment, of a G formulation at 3 lb ai/A. Soils must be previously treated at planting with a G formulation at 1.3 lb ai/A; fields must be irrigated as soon as possible following the foliar treatment. Alternatively, the registrant may elect to cancel this use permitted under EPA SLN Nos. WA840040 and WA8400386.

19/When an appropriate tolerance for residues in or on corn grain is determined, a food/feed additive tolerance must be established for flour at 2X, meal at 3X and refined oil at 6X (toxicological considerations permitting).

20/A processing study depicting the combined residues of phorate and its cholinesterase-inhibiting metabolites in wet-milled corn starch, crude oil and refined oil, and in corn grain dust from the processing of field corn bearing measurable, weathered residues is required. If residues concentrate in any product, an appropriate food/feed additive tolerance must be proposed.

21/Data are required depicting the combined residues of phorate and its cholinesterase-inhibiting metabolites in or on sorghum grain harvested 28 days following the last of two applications (soil application at planting at 1.3 lb ai/A followed by foliar application at 1 lb ai/A) using a G formulation. Aerial and ground equipment must be represented in separate tests.

Table A
Generic Data Requirements for Phorate (cont'd)

Sec. 158.240 Residue Chemistry (cont'd)

22/A processing study is required depicting the combined residues of phorate and its cholinesterase-inhibiting metabolites in milled products (flour and starch) and grain dust from the processing of sorghum bearing measurable, weathered residues. If residues concentrate in any product, appropriate food/feed additive tolerances must be proposed.

23/A processing study is required depicting combined residues of phorate and its cholinesterase-inhibiting metabolites in milled products (bran, flour, middling, and shorts) and in grain dust from the processing of wheat bearing measurable, weathered residues. If residues concentrate in any product, appropriate food/feed additive tolerances must be proposed.

24/Residue data depicting phorate residues of concern on barley grain treated with 20G formulation as a postemergent broadcast spray at a rate of 1.0 lb a.i./A are required. Grain must be harvested within 60 days of treatment. The data must reflect the maximum number of treatments desired (this must be specified on the label). Studies reflecting one band application of 1.0 lb a.i./A (0.25 oz a.i./1000 ft of row at an 8 inch row spacing) at planting using the 20G formulation are also required. These experiments should be carried out in the States of ID and WY which are where these SLNs are registered.

25/A processing study is required. The processing study for wheat will be translated to barley. Alternatively, the registrant(s) may wish to cancel the SLNs ID880003 and WY880001.

26/Since fodder is a raw agricultural commodity of field corn, a tolerance must be proposed for field corn fodder. The data reviewed previously indicated that a tolerance of 0.5 ppm would be appropriate.

27/Data are required depicting the combined residues of phorate and its cholinesterase-inhibiting metabolites in or on sorghum fodder harvested 28 days after the last of the following treatments: soil banded at-plant application of a G formulation using ground equipment at 1.3 lb ai/A followed by one foliar application at 1 lb ai/A by aerial equipment.

28/The registrant must propose appropriate tolerances for the combined residues of phorate and its cholinesterase-inhibiting metabolites in or on sorghum forage and hay based on appropriate supporting residue data. In addition, an appropriate pregrazing interval must be established for forage.

29/Since hay is a raw agricultural commodity of wheat, a tolerance must be proposed for wheat hay. The available data indicate that a tolerance of 1.5 ppm would be appropriate. Alternatively, the registrant may propose a restriction of the feeding of wheat hay to livestock.

30/Residue data depicting phorate residues of concern on barley forage, hay and straw treated with the 20G formulation as a postemergent broadcast spray at a rate of 1.0 lb a.i./A are required. The data must reflect the maximum number of treatments desired (this must be specified on the label). Data for forage only is not needed if the present label restriction prohibiting grazing of treated barley is maintained. for the postemergent application. Studies on barley forage, hay and straw reflecting one band application of 1.0 lb a.i./A at planting using the 20G formulation are also required. All experiments must be conducted in ID and WY which is where these SLNs are registered. Alternatively, the registrant(s) may wish to cancel SLNs ID880003 and WY880001.

Table A
Generic Data Requirements for Phorate (cont'd)

Sec. 158.240 Residue Chemistry (cont'd)

31/Data are required depicting residues of phorate, phorate sulfoxide, phorate sulfone, phorate oxygen analog, phorate oxygen analog sulfoxide, and phorate oxygen analog sulfone in or on cotton forage harvested 60 days following the last of two applications (banded in-furrow soil application at planting at 1.6 lb ai/A followed by sidedness soil application at 2.2 lb ai/A) using a G formulation. Also, since cotton forage is a raw agricultural commodity of cotton, a tolerance must be proposed accompanied by appropriate supporting residue data. Based on the available residue data, a tolerance of 0.2 ppm would be appropriate. Alternatively, a feeding restriction on cotton forage may be proposed.

32 The registrant must propose a tolerance for the combined residues of phorate and its cholinesterase-inhibiting metabolites in or on peanut hulls. the available data indicate that a tolerance of 0.3 ppm would be appropriate. In addition, the registrant must propose a PHI. The available data indicate that a PHI of 90 days would be suitable.

33/Since forage is a raw agricultural commodity of sugarcane, a tolerance and a pregrazing interval must be established and appropriate residue data submitted for this commodity. The residue data must include adequate samples from various posttreatment harvest intervals. Alternatively, grazing and feeding restrictions may be imposed.

34/Data are required depicting the potential for concentration of residues in bagasse processed from sugarcane bearing measurable weathered residues (The Agency had determined that a processing study on sugarcane was not needed, since it was concluded that residues of phorate are destroyed by the lime and carbonation process and do not concentrate in the processed fractions. However, the Agency now believes that bagasse fraction will not be subjected to the lime and carbonation process, and therefore residues of phorate may concentrate in the bagasse. If the data indicate a potential for concentration of residues, an appropriate food additive tolerance must be proposed.

35/Residue data are needed for dried and spent hops processed from fresh hops. Residue data depicting phorate residues of concern on hops treated with the 10G and 20G formulations at a rate of 2 to 3 lb a.i./A as a band over the row after crowns have begun to grow are required. Hops should be harvested within 42 days of treatment. Analyses should be performed on green, dried and spent (extracted) hops. Tests should be carried out in the States of WA and OR which is where the SLN's are registered. Alternatively, the registrant(s) may chose to cancel the 24(c) uses in the States of Washington (WA840044 and WA840035) and Oregon (OR880002).

36/Data are required depicting the combined phorate residues of concern in pasteurized milk; beef fat baked, boiled, broiled, and fried; and lean beef baked, boiled, broiled, and fried. Samples fortified with phorate and each of its cholinesterase-inhibiting metabolites must be subjected to each of the cooking processes specified above and all major degradation products accounted for and identified.

37/Data are required depicting the combined phorate residues of concern in whole eggs, egg yolks, and egg whites, each baked, boiled, and fried; chicken flesh plus skin without bone, and chicken flesh alone each baked, fried, and boiled. Samples fortified with phorate and each of its cholinesterase-inhibiting metabolites must be subjected to each of the cooking processes specified above and all major degradation products accounted for and identified

Table A
Generic Data Requirements for Phorate

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe For Data Submission[1/]
Sec. 158.290 Environmental Fate						
Degradation Studies - Lab						
161-1 - Hydrolysis	TGAI or PAIRA	A,B	No		Yes[2/]	9 Months
Photodegradation						
161-2 - In Water	TGAI or PAIRA	A,B	No		Yes[3/]	9 Months
161-3 - On Soil	TGAI or PAIRA	A,B	No		Yes[4/]	9 Months
161-4 - In Air	TGAI or PAIRA	A	Partially	40386307	Reserved[5/]	
Metabolism Studies - Lab						
162-1 - Aerobic Soil	TGAI or PAIRA	A,B	Partially	40077301	Yes[6/]	27 Months (12 Months - Progress Report)
162-2 - Anaerobic Soil	TGAI or PAIRA	A	No		Yes[7/]	27 Months (12 Months - Progress Report)
162-3 - Anaerobic Aquatic	TGAI or PAIRA	N/A	No		No	
162-4 - Aerobic Aquatic	TGAI or PAIRA	N/A	No		No	

Table A
Generic Data Requirements for Phorate (cont'd)

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe For Data 1/ Submission
Sec. 158.290 Environmental Fate (cont'd)						
Mobility Studies						
163-1 - Leaching and Adsorption/ Desorption	TGAI or PAIRA	A,B	Yes	40174524 40174525	No	
163-2 - Volatility (Lab)	TEP	A	No		Yes[8/]	12 Months
163-3 - Volatility (Field)	TEP	A,B	No		Reserved[9/]	
Dissipation Studies - Field						
164-1 - Soil	TEP	A	Partially	40432001, 40586506	Yes[10/]	27 Months (Acceptable Protocol- for Long Island Study 90 Days) (12 Months - Progress Report)
164-2 - Aquatic (Sediment)	TEP	N/A	No		No	
164-3 - Forestry	TEP	N/A	No		No	
164-4 - Combination and Tank Mixes	TEP	N/A	No		No	

Table A
Generic Data Requirements for Phorate (cont'd)

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe For Data [1] Submission
Sec. 158.290 Environmental Fate (cont'd)						
Dissipation Studies - Field (cont'd)						
164-5 - Soil, Long-Term	TEP	A	No		Reserved[11]	
Accumulation Studies						
165-1 - Rotational Crops (Confined)	PAIRA	A	Partially	40386311	Yes[12]	39 Months[13]
165-2 - Rotational Crops (Field)	TEP	A	No		Reserved[14]	
165-3 - Irrigated Crops	TEP	N/A	No		No	
165-4 - In Fish	TGAI or PAIRA	A,B	Partially	40386310 40386311	Yes[15]	12 Months
Sec. 158.390 Reentry Protection						
132-1 - Foliar Dissipation	TEP	A,B	No		Yes[16]	18 Months (Acceptable Protocol - 90 Days)
132-1 - Soil Dissipation	TEP	A	No		Yes[16]	18 Months (Acceptable Protocol - 90 Days)

Table A
Generic Data Requirements for Phorate (cont'd)

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe For Data 1/ Submission
Sec. 158.390^R Reentry Protection (cont'd)						
133-3 - Dermal Exposure	TEP	A,B	No		No[17]	
133-4 - Inhalation Exposure	TEP	A,B	No		No[17]	

1/Due dates refer to number of months following receipt of this Registration Standard, unless otherwise indicated.

2/The study does not fulfill this data requirement because it was not specified that the test solutions were sterile. The material balances following TLC analysis were incomplete; degradates were inadequately characterized and were not quantified; and the description of the analytical methodology was incomplete. A new study is required.

3/The study does not fulfill the requirement because it was not specified if the test solutions were sterile. Also, the material balances following TLC analysis were incomplete, degradates were inadequately characterized and were not quantified, the test solutions were not buffered, the description of the analytical methodology was incomplete, and the spectral energy distribution of the artificial light and its comparison to natural sunlight were inadequately described. A new study is required.

4/The study does not fulfill the requirement because up to 48% of the applied radioactivity remained unaccounted for. Also, the treatment rate was not specified, no precautions were taken to minimize the loss of the test substance by volatilization, the description of the analytical methodology was incomplete, the photolysis chamber was not adequately described, and the spectral energy distribution of the artificial light and its comparison to natural sunlight were inadequately presented. A new study is required.

5/The study submitted only partially fulfills the data requirement because in the photolysis in air sampling bags study, the test substance was incompletely characterized, the temperature was 52 to 60 ^{0}C rather than 30 ^{0}C, the intensity of the natural sunlight was not reported, and the material balances were incomplete; and in the photolysis in a large volume atmosphere chamber study, the temperature was 51 to 59 ^{0}C rather than 30 ^{0}C, the intensity of the natural sunlight was not reported, degradates were not characterized, and material balances were not reported. However, the data requirement is now reserved pending receipt and evaluation of an acceptable laboratory volatility study.

Table A
Generic Data Requirements for Phorate (cont'd)

Sec.s 158.290, 158.390, and 158.440 Environmental Fate (cont'd)

6/The study does not fulfill the requirement because the purity of the test substance was not specified. Also, the soil samples and soil extracts were stored prior to analysis, but storage stability data were not provided. Within 90 days, the registrant must inform the Agency of the option chosen (1) to provide the missing information to upgrade the study or, (2) to submit a new study. If the registrant chooses to submit a new study, the data are due 27 months from receipt of the Standard. An annual report is due 12 months from receipt of the Standard, and annual reports are due thereafter. If the registrant chooses to provide the missing information, the data are due 6 months from receipt of the Standard.

7/The study does not fulfill the requirement because material balances for samples taken at 30 and 39 days after anaerobic conditions were established were incomplete, and the experimental design was inadequate to accurately assess the degradation of phorate under anaerobic conditions. In addition, the purity of the test substance was not specified and soil samples and soil extracts were stored prior to analysis, but storage stability data were not provided. A new study is required. The data are also required because of a concern for the potential exposure of waterfowl to phorate residues in wetlands.

8/The study does not fulfill the requirement because material balances were incomplete, soil from the volatilization samples was not sampled immediately posttreatment, and the relative humidity was not reported. A new study is required.

9/This data requirement is now reserved pending the results of the laboratory volatility study.

10 A field terrestrial dissipation study is required to be conducted in accordance with the Subdivision N Guidelines, if the registrant cannot provide the missing information (reporting of field maintainance practices at Danville, Iowa, specify time soil samples were frozen prior to analysis, provide freezer storage stability data, and clarify why the concentration of phorate in the 0-3" depth was 10.2 ppm immediately posttreatment, rather than the expected 1 ppm based on the reported application rate of 11 lb ai/A). Within 90 days, the registrant must inform the Agency of the option chosen: (1) to provide the missing information to upgrade the study or, (2) to submit a new study. If the registrant chooses to submit a new study, the data are due 27 months from receipt of the Standard. An annual report is due 12 months from receipt of the Standard. If the registrant chooses to provide the missing information, the data are due 6 months from receipt of the Standard.

In addition, a terrestrial field dissipation study must be conducted on sandy loam soil in Long Island, NY. Soil core samples must be collected down to 3 feet. All samples must be analyzed for phorate and the phorate sulfoxide and sulfone degradates. The minimum limits of detection (MDL) for detecting phorate, phorate sulfoxide, and sulfone in soil should approach 10 ppb, if feasible. The current method of analysis for phorate, the sulfoxide and sulfone degradates uses an MDL that is too high. A protocol is required. The registrant must discuss the MDL with the Agency prior to initiating the study. Following the submission and evaluation of such a study, the Agency will determine the need for ground water monitoring studies.

Table A
Generic Data Requirements for Phorate (cont'd)

Sec.s 158.290, 158.390, and 158.440 Environmental Fate (cont'd)

11/Data will be required if the results from the aerobic soil metabolism (162-1) and/or soil field dissipation studies (164-1) show that 50% phorate remains in the soil prior to the recommended subsequent application.

12/The study only partially fulfills the requirement because not all of the residues of the test substances (phorate, phorate sulfoxide, and phorate sulfone) were completely characterized and except for one sampling interval, the residues in the soil were not analyzed at the time of harvest of the rotational crop. Also, the study was conducted with 1.5 lb ai/A instead of the maximum label rate. It should be noted that if this study is made acceptable upon evaluation of additional data listed in the data evaluation record, it will only support application rates on pesticide labeling of up to 1.5 lb ai/A.

13/Within 90 days, the registrant must inform the Agency of the option chosen: (1) to provide the missing information to upgrade the study or, (2) to submit a new study. If the registrant chooses to submit a new study, the data are due 39 months from receipt of the Standard. An annual report is due 12 months from receipt of the Standard, and interim reports are due annually thereafter. If the registrant chooses to provide the missing information, the data are due 6 months from receipt of the Standard.

14/No data were submitted by the registrant. However, this requirement is now reserved, depending on the results of the confined rotational crop study.

15/The study only partially fulfills the requirement because the test substance was incompletely characterized, the fish may only have been exposed to the parent compound, and degradate characterization results from the fish tissue samples were reported in terms of percent recovered radioactivity from the TLC plates rather than percent of total (initial) sample radioactivity. A new study is required.

16/A foliar dislodgable study is required for corn. Soil dissipation studies are required for peanuts and potatoes (protocols have already been reviewed for these crops). No data are required for foliar dislodgable residues for peanuts and potatoes. For other end-uses, the registrant is required to propose an acceptable reentry interval based upon data (1) on dissipation of residues (decline curve), on human exposure to those residues, and on toxicity of the residue, or (2) on the determination of that time beyond which there are no detectable dislodgeable or inhalable residues remaining in the worker environment.

17/These data may be submitted at the registrant's option.

Table A
Generic Data Requirements for Phorate

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe For Data Submission 1/
Sec. 158.340 Toxicology						
81-1 - Acute Oral - Rat	TGAI	A,B	Yes	00126343	No	
81-2 - Acute Dermal	TGAI	A,B	Yes	00126343	No	
81-3 - Acute Inhalation	TGAI	A,B	Yes	00126343	No	
81-4 - Eye Irritation	TGAI	A,B	No		No2/	
81-5 - Dermal Irritation	TGAI	A,B	No		No2/	
81-6 - Dermal Sensitization	TGAI	A,B	No		No2/	
81-7 - Acute Delayed Neurotoxicity	TGAI	A,B	Yes	00152640	No	
Subchronic Testing						
82-1 - 90-Day Feeding -						
Rodent	TGAI	A,B	Yes	00056714	No3/	
Non-rodent	TGAI	A,B	No		No4/	

Table A
Generic Data Requirements for Phorate (cont'd)

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe For Data 1/ Submission
Sec. 158.340 Toxicology						
Subchronic Testing (cont'd)						
82-2 - 21-Day Dermal	TGAI	A,B	No		No[2]/	
82-3 - 90-Day Dermal	TGAI	A,B	No		No[5]/	
82-4 - 90-Day Inhalation	TGAI	N/A	No		No[6]/	
82-5 - 90-Day Neurotoxicity	TGAI	A,B	No		No[7]/	
Chronic Testing						
83-1 - Chronic Testing						
- Rodent	TGAI	A,B	Partially	00122774, 00122773	No[8]/	
- Nonrodent	TGAI	A,B	Yes	40174527	No	
83-2 - Oncogenicity						
- Rat	TGAI	A,B	Yes	00122774	No	
- Mouse	TGAI	A,B	Partially	00122774	Reserved[9]/[14]/	

Table A
Generic Data Requirements for Phorate (cont'd)

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe For Data[1] Submission
Sec. 158.340 Toxicology						
Chronic Testing (cont'd)						
83-3 - Teratogenicity - Rat	TGAI	A,B	Yes	00122775	No	
- Rabbit	TGAI	A,B	Yes	40174528	No	
83-4 - Reproduction	TGAI	A,B	Yes	00092853	No	
Mutagenicity Testing						
84-2 - Gene Mutation	TGAI	A,B	Yes	00132582, 00151633	No	
84-2 - Chromosome Aberration	TGAI	A,B	Yes	00132582, 00155597	No	
84-4 - Other Mechanisms of Mutagenicity	TGAI	A,B	Yes	00132582	No	
Special Testing						
85-1 - General Metabolism	PAI or PAIRA	A,B	Partially	40291601	Yes[10]	24 Months (Acceptable Protocol - 90 Days) (12 Months - Progress Report)

Table A
Generic Data Requirements for Phorate (cont'd)

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe For Data 1/ Submission
Sec. 158.340 Toxicology						
Special Testing (cont'd)						
Eye Effects						
a. Acute Oral (Rat) Study		A,B	No		Yes11/	9 Months
b. . Subchronic Oral (Rat) Study		A,B	No		Yes11/	15 Months
c. 6-Month Oral Study (Dog, Rabbit, or Monkey)		A,B	No		Yes11/	18 Months
Oxidation Products		A,B	No		Reserved12/	
Product Integrity Study		A,B	Yes	40586507	No12/	
Short-term Mouse Study		A,B	No		Yes14/	12 Months (90 Days - Acceptable Protocol)

Table A
Generic Data Requirements for Phorate (cont'd)

Sec. 158.340 Toxicology (cont'd)

1/Due dates refer to the number of months following receipt of this Registration Standard, unless otherwise indicated.

2/The data are not required, since the highly toxic nature of phorate prohibits the administration of dosage levels that could possibly induce an adverse effect other than the possible inhibition of cholinesterase activity. Also, the subchronic dermal study can be expected to show no effect other than cholinesterase inhibition and subsequent lethality secondary to this inhibition.

3/This study was considered deficient because histopathology was performed on 3 (not 10) rats/sex in the control and test groups. However, the NOEL and LEL, which were based on the most sensitive endpoint (inhibition of cholinesterase activity), were acceptable as well as consistent with those established in a non-rodent study. A new study is not required.

4/This study is not required because an acceptable chronic study in a non-rodent species is available.

5/This study is not required because the registered use patterns of phorate should not result in repeated dermal contact.

6/This study is not required because the registered use patterns of phorate should not result in repeated inhalation exposure.

7/This study is not required because there was no indication of delayed neurotoxicity in the acute study in hens.

8/Although the NOEL, which was based on inhibited cholinesterase activity, was not achieved in the submitted chronic feeding study in rats, a NOEL, based on the same endpoint, was achieved in a subchronic study in rats.

9/The requirement for a new mouse oncogenicity study is reserved pending Agency review and evaluation of the required short-term mouse study.

10/Submitted data were from a study that was performed with male rats only. A comparable study in female rats is required. The administration of a single dosage level in the male study is acceptable since the high acute oral toxicity of this compound does not allow much flexibility in dosage selection. A lower dose level might be detrimental to quantitative work with minor metabolites while a higher dose might cause mortalities. However, since females are generally more sensitive to adverse effects from phorate than males, it may be necessary to administer a lower dosage level to females than that (0.8 mg/kg) given to males. A protocol must be submitted within 90 days of receipt of this Standard.

11/Since data from various studies have demonstrated adverse ocular effects from other organophosphates, data are now being required to investigate the potential ocular toxicity of phorate special acute and subchronic studies are required confirm or deny the potential for phorate to cause adverse eye effects as follows:

Table A
Generic Data Requirements for Phorate (cont'd)

Sec. 158.340 Toxicology (cont'd)

a. Acute oral (rat) study. Acute sublethal doses must be administered. Tests are to be performed pretest, at 4 days and repeated at intervals until full recovery. Observations must include (1) cholinesterase activity (blood) and (2) retinal electrical activity (electroretinography).

b. Subchronic oral (rat) study. Test must include 3 orally treated and 1 control group, 10 rats/sex/group. Observations must be made pretest, and at intervals for at least 90 days; doses must on the results of the acute study. Observations must also include (1) cholinesterase activity (blood, brain at termination); (2) retinal electrical activity (electroretinography); (3) ophthalmoscopic observations; (4) fundus observations/photographs; (5) clinical observations of potential cholinergic signs; (6) body weights and; (7) histopathology of the eye, light and EM, including intra and extraocular muscle, optic nerve and retina.

c. Six month oral (dog or rabbit or monkey) study. Test must include 3 orally treated and one control group, 5 animals/sex/group. Observations must be made pretest and at intervals for at least 6 months. Observations must include (1) cholinesterase activity (RBC, plasma; at termination brain, oculomotor muscle, retina); (2) retinal electrical activity (electroretinography); (3) corneal sensitivity; (4) slit lamp biomicroscopic examinations; (5) corneal thickness; (6) corneal curvature; (7) ophthalmoscopic/fundus observations/photographs; (8) intraocular pressure; (9) refractivity of cornea and lens; (10) clinical observations of potential cholinergic signs; and (11) body weights and histopathology of the eye; light and EM, including intra- and extraocular muscle, optic nerve and retina.

12/Residue data submitted in response to the 1984 Standard have shown that oxidation products of phorate in plants are so low that they are of little concern. However, the data base for residue chemistry is not complete. Additional toxicity studies with the oxidative metabolites may be required, if significant residue levels of the oxidative metabolites are detected in the required residue studies.

13/Based on the product integrity study submitted in response to the 1984 Standard under this data requirement, the Agency concluded that the 20G formulation does not pose an inhalation hazard under normal use conditions, and that therefore an inhalation study using a 20G formulation is not required.

14/Based on a reevaluation of the mouse oncogenicity study, the evidence does not show that an MTD was attained in this study. The Agency is requiring that a short-term study be performed to determine if any of the dietary levels administered in the mouse oncogenicity study will inhibit acetylcholinesterase activity (plasma, brain and/or red cell). The registrant must discuss details of the test protocol prior to initiating the study. The mouse oncogenicity study may be upgraded depending on the results of this study.

Table A
Generic Data Requirements for Phorate

Data Requirement	Test Substance	Pattern	Does EPA Have Data to Satisfy This Requirement?	Use Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe For Data 1/ Submission
Sec. 158.490 - Wildlife and Aquatic Organisms						
Avian and Mammalian Testing						
71-1 - Avian Single Dose Oral LD_{50}	TGAI	A,B	Yes	001600012/, 000205602/, 050083632/	No	
71-2 - Avian Dietary LC_{50}						
- Upland Game Bird	TGAI	A,B	Yes	00022923	No	
- Waterfowl	TGAI	A,B	Yes	00022923	No	
71-3 - Wild Mammal Toxicity	TGAI	A,B	Yes	00162745	No	
71-4 - Avian Reproduction						
- Upland Game Bird	TGAI	A,B	No		Yes3/	24 Months (12 Months - Progress Report)
- Waterfowl	TGAI	A,B	Yes	00158334	No	
71-5 - Simulated Field Testing for Birds and Mammals	TEP	A,B	Yes	00074623,00084503 00074624,00074625, 00074626,00074627, 00087553,00092832, 00092834,00052237,	No2/	

Table A
Generic Data Requirements for Phorate (cont'd)

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe For Data[1] Submission
Sec. 158.490 - Wildlife and Aquatic Organisms						
Avian and Mammalian Testing (cont'd)						
71-5 - Actual Field Testing for Birds and Mammals	TEP	A,B	Yes	40165901	No	
Aquatic Organism Testing						
72-1 - Freshwater Fish LC_{50}						
- Warmwater	TGAI	A,B	Yes	00003503	No	
	TEP	A,B	Yes	00090490, 00161822	No[4]	
- Coldwater	TGAI	A,B	Yes	00003503	No	
	TEP	A,B	Yes	00090491, 00161823, 00161824	No[4]	
72-2 - Freshwater Invertebrate LC_{50}	TGAI	A,B	Yes	00003503, 00085219, 00097842	No[2]	
	TEP	A,B	Yes	00161825, 00161826	No[5]	

Table A
Generic Data Requirements for Phorate (cont'd)

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe For Data 1/ Submission
Sec. 158.490 - Wildlife and Aquatic Organisms						
Aquatic Organism Testing (cont'd)						
72-3 - Estuarine and Marine Organisms LC_{50}						
- Fish	TGAI	A,B	Yes	00066341	No	
	TEP	A,B	Yes	40001802	No5/	
72-3 - Estuarine and Marine Organisms LC_{50} (cont'd)						
- Shrimp	TGAI	A,B	Yes	00066341	No	
	TEP	A,B	No		Yes5,6/	12 Months
- Oyster	TGAI	A,B	Yes	00066341	No	
	TEP	A,B	Yes	40004201	No5/	
72-4 - Fish Early Life Stage and Invertebrate Life Cycle						
- Freshwater						
- Fish	TGAI	A,B	No		Yes7/	15 Months
- Invertebrates	TGAI	A,B	Partially	00158336	Yes8/	15 Months

Table A
Generic Data Requirements for Phorate (cont'd)

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe For Data 1/ Submission
Sec. 158.490 - Wildlife and Aquatic Organisms						
Aquatic Organism Testing (cont'd)						
- Estuarine						
- Fish	TGAI	A,B	Partially	00066341	Yes9/	15 Months
- Invertebrates	TGAI	A,B	Partially	00066341	Yes9/	15 Months
72-5 - Fish Life Cycle	TGAI	A,B	No		Reserved10/	
72-6 - Aquatic Organisms Accumulation (Fish)	TGAI	A,B	No		Reserved10/	
72-7 - Simulated or Actual Field Testing Aquatic Organisms	TEP	A,B	No		Yes11/	January, 1991

1/Due dates refer to number of months following receipt of this Registration Standard, unless otherwise indicated.
2/Collectively, the data satisfy the requirement.
3/The submitted bobwhite study was determined to be unacceptable, since the production of eggs in 25 percent of the control pairs was significantly below normal. A new study is required. Also, the mallard reproduction study indicated that long-term exposure significantly impairs reproduction. The requirement for a reproduction study of waterfowl in wetland areas is reserved pending on the results of the environmental fate data.

Table A
Generic Data Requirements for Phorate (cont'd)

Sec. 158.490 - Wildlife and Aquatic Organisms (cont'd)

4/The TEPs were Thimet 600 EC (90490, 90491) and Thimet 20G (161822, 161823, 161824). Liquid formulations are no longer registered. The studies with Thimet 20G satisfy any granular formulation of phorate up to 20% ai.

5/The TEP was Thimet 20G. Acceptable studies done with this formulation satisfy any granular formulation of phorate up to 20% ai.

6/The submitted study does not fulfill the data requirement because the test specimens were in different age classes and different stages of development. A new study is required.

7/The submitted study was determined to be unacceptable because the mortality of the control fish embryos was excessively high (> 50%). A new study is required.

8/The submitted study was determined to be unacceptable because the raw data needed to analyze the study were not submitted. Upon submission of all raw data on mortality and reproduction for each replicate daphnid chamber for each day that observations were made on survival and offspring production, the evaluation of the study will be completed. Within 90 days, the registrant must inform the Agency of the option chosen: 1) to provide the missing information to upgrade the study, or 2) to submit a new study. If the registrant chooses to provide the missing information, these data are due 6 months from receipt of the Standard. If the registrant chooses to submit a new study, the data are due 15 months from receipt of the Standard.

9/These studies are required based upon the laboratory bioassays and estimated/actual residues in the environment. The estuarine mysid shrimp life cycle test and sheepshead minnow embryo-juvenile test are deficient but can fulfill data requirements upon submission of additional data. Raw data for each replicate on mortality, hatching, and size of juveniles, must be submitted for the sheepshead minnow test so that the statistical analyses can be verified. The DO and pH measurements and raw data for each replicate must be submitted for the mysid shrimp test so effects on survivability and reproduction can be verified. Submission of these missing data were required in the Guidance Document, 1984. If these data are unavailable, new studies are required. Within 90 days, the registrant must inform the Agency of the option chosen: (1) to provide the missing information to upgrade the study, or (2) to submit a new study. If the registrant chooses to submit a new study, the data are due 15 months from receipt of this Standard. If the registrant chooses to provide the missing information, these data are due 6 months from receipt of this Standard.

10/This study is reserved pending the results of environmental fate data and a fish early life stage study.

11/A pond study consisting of two reference ponds and two treatment ponds in the corn region of Iowa is currently underway. The schedule calls for a baseline study to be conducted in 1988 and the treatment study to be conducted in 1989. The new due date for this submission of this study is January, 1991.

Table A
Generic Data Requirements for Phorate

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe For 1/ Submission
Sec. 158.590 Nontarget Insects						
NONTARGET INSECT TESTING - POLLINATORS						
141-1 - Honey Bee Acute Toxicity	TGAI	A,B	No		No[2/]	
41-2 - Honey Bee - Toxicity of Residues on Foliage	TEP	A,B	No		No[2/]	
141-4 - Honey Bee Subacute Feeding Study	TEP	A,B	No		No[2/]	
141-5 - Field Testing for Pollinators	TEP	A,B	No		No[2/]	
NONTARGET INSECT TESTING - AQUATIC INSECTS						
142-1 - Acute Toxicity to Aquatic Insects	Reserved[3/]					
142-2 - Aquatic Insect Life Cycle Study	Reserved[3/]					
142-3 - Simulated or Actual Field Testing for Aquatic Insects	Reserved[3/]					

Table A
Generic Data Requirements for Phorate (cont'd)

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe For 1/ Submission
Sec. 158.590 Nontarget Insects (cont'd)						
NONTARGET INSECT TESTING - PREDATORS AND PARASITES						
143-1 thru 143-3	Reserved[3]					

1/Due dates refer to the number of months following receipt of this Registration Standard, unless otherwise indicated.

2/This study is not required. Since this pesticide is registered only in granular form, there is no potential for bee exposure.

3/This requirement is reserved pending development of test methodology and/or decisions as to whether data should be required.

Table B
Product-Specific Data Requirements for Manufacturing-Use Products Containing Phorate

Data Requirement	Test Substance	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe For Data Submission[1]
Part 158, Subpart C - Product Chemistry					
Product Identity and Composition					
61-1 - Product Identity and Disclosure of Ingredients	MP	Partially	00146524,	Yes[2]	9 Months
61-2 - Description of Beginning Materials and Manufacturing Process	MP	Partially	00146524, 00155595	Yes[3]	9 Months
61-3 - Discussion of Formation of Impurities	MP	Partially	00146524, 00158941	Yes[4]	9 Months
Analysis and Certification of Product Ingredients					
62-1 - Preliminary Analysis of Product Samples	MP	Partially	00146524	Yes[5]	12 Months
62-2 - Certification of Ingredient Limits	MP	Partially	00146524	Yes[6]	12 Months
62-3 - Analytical Methods to Verify Certified Limits	MP	Partially	00146524, 00149814	Yes[7]	12 Months

Table B
Product-Specific Data Requirements for Manufacturing-Use Products Containing Phorate (cont'd)

Data Requirement	Test Substance	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe For Data Submission [1]
Part 158, Subpart C - Product Chemistry					
Physical and Chemical Characteristics (cont'd)					
Physical and Chemical Characteristics					
63-2 - Color	MP	Yes	00146524, 00149814	No	
63-3 - Physical State	MP	Yes	00146524, 00149814	No	
63-4 - Odor	MP	Yes	00146524, 00158941	No	
63-7 - Density, Bulk Density, or Specific Gravity	MP	Yes	00146524, 00149814	No	
63-12 - pH	MP	Yes	00146524, 00158941	No[8]	
62-14 - Oxidizing or Reducing Action	MP	Partially	00146524, 00158941	Yes[9]	9 Months
62-15 - Flammability	MP	Partially	00146524, 00158941	Yes[10]	9 Months
63-16 - Explodability	MP	Partially	00146524, 00158941	Yes[11]	9 Months
63-17 - Storage Stability	MP	Partially	00146524, 00158941	Yes[12]	15 Months
63-18 - Viscosity	MP	Partially	00146524, 00158941	Yes[13]	9 Months
63-19 - Miscibility	MP	Yes	00146524, 00158941	No[14]	

Table B
Product-Specific Data Requirements for Manufacturing-Use Products Containing Phorate (cont'd)

Data Requirement	Test Substance	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe For Data 1/ Submission
Part 158, Subpart C - Product Chemistry					
Physical and Chemical Characteristics (cont'd)					
63-20 - Corrosion Characteristics	MP	Partially	00146524	Yes15/	15 Months
Other Requirements					
64-1 - Submittal of Samples	N/A				

1/Due dates refer to the number of months following receipt of this Registration Standard, unless otherwise indicated.

2/For the 89.4% T (EPA Registration No. 2749-106), the registrant must provide a fully completed EPA Form 8570-4 that includes the correct chemical name, the molecular, structural, and empirical formula, and upper certified limit for each impurity for which a certified limit is required. For the Cyanamid 85% Ts (EPA Registration Nos. 241-212 and 241-213), the certified limits of each active ingredient must be provided. Also, the name and upper certified limit must be provided for each impurity or group of impurities for which a certified limit is required. The information on ingredient limits must be submitted on EPA Form 8570-4 (Rev. 2-85).

3/Information must be submitted for the American Cyanamid 85% Ts (EPA Registration Nos. 241-213 and 241-212) and the Aceto Chemicals 89.4% T (EPA Registration No. 2749-106) regarding the relative amounts of beginning materials and the order in which they are added, the equipment used to produce each intermediate and the final product, reaction conditions, the duration of each step of the process, and quality control measures. In addition, the name and address of the manufacturer, producer, or supplier of each beginning material used in the manufacture of each product must be provided for the Aceto product, as well as a statement regarding the nature of the process (batch or continuous), and flow chart with chemical equations of each intended chemical reaction.

4/For the 89.4% T (EPA Registration No. 2749-106), a detailed discussion must be submitted of all impurities that are or may be present at ≥ 0.1%, based on knowledge of the beginning materials, chemical reactions (intended and side) in the manufacturing process, and any contamination during and after production.]

5/Five or more representative batches of the Aceto 89.4% T (EPA Registration No. 2749-106) must be analyzed for the amount of active ingredient and each impurity for which certified limits are required. Complete validation data

Table B
Product-Specific Data Requirements for Manufacturing-Use Products Containing Phorate (cont'd)

[1]158.150-190 Product Chemistry Footnotes (cont'd)

(accuracy and precision) must be submitted for the Aceto 89.4% T and the American Cyanamid 85% Ts (EPA Registration Nos. 241-213 and 241-212).

6/For the 89.4% T (EPA Registration No. 2749-106) correct chemical names of the impurities must be associated with the certified limits, and a statement of how the certified limits were determined must be provided. For the Cyanamid 85% Ts (EPA Registration Nos. 241-212 and 241-213), upper and lower limits for each active ingredient, upper limits for each impurity present at ≥ 0.1% (w/w), and each additional "toxicologically significant" impurity that may be present at < 0.1% must be certified. An explanation of how each limit was established (e.g., sample analysis using a validated analytical procedure, quantitative estimates based on the amounts of ingredients used, etc.) must be provided, along with information on the accuracy and precision of the procedures used. Certifications must be submitted on EPA Form 8570 (Rev. 2-85) for all manufacturing-use products.

7/For the 89.4% T (EPA Registration No. 2749-106), analytical methods for the verification of certified limits must be provided, including a full description of how each of the impurities is determined. The methods must be accompanied by validation studies indicating its accuracy and precision. Validation data must also be submitted for the analytical methods used for the 85% Ts (EPA Registration Nos. 241-213 and 241-212).

8/Data not required because the test substance is not dispersible in water.

9/No useful data were submitted to fulfill the requirements for the 85% Ts (EPA Registration Nos. 241-213 and 241-212) or for the 89.4% T (EPA Registration No. 2749-106). Data are required if the product contains oxidizing or reducing agents.

10/The submitted data do not satisfy the requirements for the 85% Ts (EPA Registration Nos. 241-213 and 241-212) or for the 89.4% T (EPA Registration No. 2749-106) because a flashpoint and a method of determination was not provided. These data are required if the product is a combustible liquid.

11/The submitted data do not satisfy the requirements for the 85% Ts (EPA Registration Nos. 241-213 and 241-212) and the 89.4% T (EPA Registration No. 2749-106) because the methodology was not described. Data are required if the product is potentially explosive.

12/The submitted data do not satisfy the requirements for the 85% Ts (EPA Registration Nos. 241-213 and 241-212) because the analytical method was not specified. The submitted information do not satisfy these requirements for the 89.4% T (EPA Registration No. 2749-106) because the appropriate test conditions were not followed.

13/The submitted data satisfy the requirements for the 85% Ts (EPA Registration Nos. 241-213 and 241-212). The submitted information do not satisfy these requirements for the 89.4% T (EPA Registration No. 2749-106) because viscosity must be reported in appropriate conventional unit and determined at 20 or 25 °C. Data are required if the product is a liquid.

14/Data not required because none of the phorate manufacturing-use products are emulsifiable liquids to be diluted with petroleum solvents.

Table B
Product-Specific Data Requirements for Manufacturing-Use Products Containing Phorate (cont'd)

[1]158.150-190 Product Chemistry Footnotes (cont'd)

15/The submitted data satisfy the requirements for the 85% Ts (EPA Registration Nos. 241-213 and 241-212). The submitted information do not satisfy these requirements for the 89.4% T (EPA Registration No. 2749-106) because no test substances or test conditions were specified. The following additional data are required: As required i 40 CFR 158.190 and more fully described in the Pesticide Assessment Guidelines, Subdivision D, data must be submitted for the 89.4% T (EPA Registration No. 2749-106) regarding vapor pressure, octanol/water partitioning coefficient, stability, oxidizing or reducing action, flammability, explodability, storage stability, viscosity, and corrosion characteristics. Data on boiling point, solubility, vapor pressure, octanol/water partitioning coefficient, stability, oxidizing or reducing action, flammability, explodability, and storage stability must be submitted for the 85% Ts (EPA Registration Nos. 241-213 and 241-212).

Table B
Product-Specific Data Requirements for Manufacturing-Use Products Containing Phorate

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe For Data 1/ Submission
Sec. 158.340 Toxicology						
Acute Testing						
81-1 - Acute Oral - Rat	MP[2]	A,B	Yes	00126343	No[3]	
81-2 - Acute Dermal	MP	A,B	Yes	00126343	No[3]	
81-3 - Acute Inhalation - Rat	MP	A,B	Yes	00126343	No[3]	
81-4 - Eye Irritation - Rabbit	MP	A,B	No		No[4]	
81-5 - Dermal Irritation						
- Rabbit	MP	A,B	No		No[4]	
81-6 - Dermal Sensitization						
- Guinea Pig	MP	A,B	No		No[5]	

1/Due dates refer to number of months following receipt of the Registration Standard, unless otherwise indicated.
2/Formulation intermediates are included in the category of manufacturing-use products.
3/Data are adequate to support currently registered MP products containing phorate at 85% a.i. and above.
4/Testing is not required since phorate is too toxic to allow the use of appropriate dose levels required for adequate testing.
5/Testing is not required. In addition to phorate's high acute toxicity, the chemical structure of phorate does not indicate a possible dermal sensitization potential.

Table C
Product-Specific Data Requirements for End-Use Products Containing Phorate

Data Requirement	Test Substance	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe For Data Submission[1]
Part 158, Subpart C - Product Chemistry					
Product Identity and Composition					
61-1 - Product Identity and Disclosure of Ingredients	EP	No		Yes	9 Months
61-2 - Description of Beginning Materials and Manufacturing Process	EP	No		Yes	9 Months
61-3 - Discussion of Formation of Impurities	EP	No		Yes	9 Months
Analysis and Certification of Product Ingredients					
62-1 - Preliminary Analysis of Product Samples	EP	No		Yes[2]	12 Months
62-2 - Certification of Ingredient Limits	EP	No		Yes	12 Months
62-3 - Analytical Methods to Verify Certified Limits	EP	No		Yes	12 Months

Table C
Product-Specific Data Requirements for Manufacturing-Use Products Containing Phorate (cont'd)

Data Requirement	Test Substance	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe For Data 1/ Submission
Part 158, Subpart C - Product Chemistry					
Physical and Chemical Characteristics (cont'd)					
Physical and Chemical Characteristics					
63-2 - Color	EP	No		Yes	9 Months
63-3 - Physical State	EP	No		Yes	9 Months
63-4 - Odor	EP	No		Yes	9 Months
63-7 - Density, Bulk Density, or Specific Gravity	EP	No		Yes	9 Months
63-12 - pH	EP	No		No[3/]	
62-14 - Oxidizing or Reducing Action	EP	No		Yes	9 Months
62-15 - Flammability	EP	No		No[3/]	
63-16 - Explodability	EP	No		Yes	9 Months
63-17 - Storage Stability	EP	No		Yes	15 Months
63-18 - Viscosity	EP	No		No[3/]	
63-19 - Miscibility	EP	No		No[3/]	

Table C
Product-Specific Data Requirements for Manufacturing-Use Products Containing Phorate (cont'd)

Data Requirement	Test Substance	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe For Data 1/ Submission
Part 158, Subpart C - Product Chemistry					
Physical and Chemical Characteristics (cont'd)					
63-20 - Corrosion Characteristics	EP	No		Yes	15 Months
Other Requirements					
64-1 - Submittal of Samples	N/A				

1/Due dates refer to the number of months following receipt of this Registration Standard, unless otherwise indicated.
2/Only required for products produced by an integrated system.
3/Not required, since all EP products are granular formulations.

Table C

Product Specific Data Requirements for End-Use Products Containing Phorate Granular Products 10-20%

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe For Data Submission[1]
Sec. 158.340 Toxicology						
Acute Testing						
81-1 - Acute Oral - Rat	TEP[2]	All	Yes	00093038	No	
81-2 - Acute Dermal Toxicity - Rabbit	TEP	All	No		Yes	9 Months
81-3 - Acute Inhalation Toxicity - Rat	TEP	All	Partially	40586507	Yes[3]	9 Months
81-4 - Primary Eye Irritation - Rabbit	TEP	All	Yes	00093038	No	
81-5 - Primary Dermal Irritation - Rabbit	TEP	All	Yes	00093039	No	
81-6 - Dermal Sensitization - Guinea Pig	TEP	All	No		No[4]	

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[1] Due dates refer to the number of months following receipt of the Registration Standard, unless otherwise indicated. Studies using the 15G or 20G will suffice for a single active granular formulation between 10% and 20%.

[2] Includes both single active ingredient and multiple active ingredient formulations.

[3] Not required for the Thimet 20G (EPA Reg No. 241-212) product. Required for other formulation types.

[4] Not required because acute dermal and eye studies indicate that the product is too toxic to test.

Table C
Product Specific Data Requirements for End-Use Products Containing Phorate Granular Products 1-10%

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe For Data Submission[1]
Sec. 158.340 Toxicology						
Acute Testing						
81-1 - Acute Oral - Rat	TEP[2]	All	No		Yes	9 Months
81-2 - Acute Dermal Toxicity - Rabbit	TEP	All	No		Yes	9 Months
81-3 - Acute Inhalation Toxicity - Rat	TEP	All	No		Yes	9 Months
81-4 - Primary Eye Irritation - Rabbit	TEP	All	No		Yes	9 Months
81-5 - Primary Dermal Irritation - Rabbit	TEP	All	No		Yes	9 Months
81-6 - Dermal Sensitization - Guinea Pig	TEP	All	No		Yes	9 Months

---

[1] Due dates refer to the number of months following receipt of the Registration Standard, unless otherwise indicated.
[2] Includes both single active ingredient and multiple active ingredient formulations.

Table C
Product Specific Data Requirements for End-Use Products Containing Phorate Granular Products < 1%

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe For Data Submission[1]
Sec. 158.340 Toxicology						
Acute Testing						
81-1 - Acute Oral - Rat	TEP[2]	All	No		Yes	9 Months
81-2 - Acute Dermal Toxicity - Rabbit	TEP	All	No		Yes	9 Months
81-3 - Acute Inhalation Toxicity - Rat	TEP	All	No		Yes[3]	9 Months
81-4 - Primary Eye Irritation - Rabbit	TEP	All	No		Yes	9 Months
81-5 - Primary Dermal Irritation - Rabbit	TEP	All	No		Yes	9 Months
81-6 - Dermal Sensitization - Guinea Pig	TEP	All	No		Yes	9 Months

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1/Due dates refer to the number of months following receipt of the Registration Standard, unless otherwise indicated.
2/Includes both single active ingredient and multiple active ingredient formulations.
3/Required if product consists of; or produces inhalable particles, such as fines, when mixed, loaded or used.

II. LABELING APPENDICES

SUMMARY-1

LABEL CONTENTS

40 CFR 156.10 requires that certain specific labeling statements appear at certain locations on the label. This is referred to as format labeling. Specific label items listed below are keyed to the table at the end of this Appendix.

Item 1. PRODUCT NAME - The name, brand or trademark is required to be located on the front panel, preferably centered in the upper part of the panel. The name of a product will not be accepted if it is false or misleading.

Item 2. COMPANY NAME AND ADDRESS - The name and address of the registrant or distributor is required on the label. The name and address should preferably be located at the bottom of the front panel or at the end of the label text.

Item 3. NET CONTENTS - A net contents statement is required on all labels or on the container of the pesticide. The preferred location is the bottom of the front panel immediately above the company name and address, or at the end of the label test. The net contents must be expressed in the largest suitable unit, e.g., "1 pound 10 ounces" rather than "26 ounces." In addition to English units, net contents may be expressed in metric units. [40 CFR 156.10(d)]

Item 4. EPA REGISTRATION NUMBER - The registration number assigned to the pesticide product must appear on the label, preceded by the phrase "EPA Registration No.," or "EPA Reg. No." The registration number must be set in type of a size and style similar to other print on that part of the label on which it appears and must run parallel to it. The registration number and the required identifying phrase must not appear in such a manner as to suggest or imply recommendation or endorsement of the product by the Agency. [40 CFR 156.10(e)]

Item 5. EPA ESTABLISHMENT NUMBER - The EPA establishment number, preceded by the phrase "EPA Est." is the final establishment at which the product was produced, and may appear in any suitable location on the label or immediate container. It must also appear on the wrapper or outside container of the package if the EPA establishment number on the immediate container cannot be clearly read through such wrapper or container. [40 CFR 156.10(f)]

Item 6A. INGREDIENTS STATEMENT - An ingredients statement is required on the front panel. The ingredients statement must contain the name and percentage by weight of each active ingredient and the total percentage by weight of all inert ingredients. The preferred location is immediately below the product name. The ingredients statement must run parallel with, and be clearly distinguished from, other text on the panel. It must not be placed in the body of other text. [40 CFR 156.10(g)]

Item 6B. POUNDS PER GALLON STATEMENT - For liquid agricultural formulations, the pounds per gallon of active ingredient must be indicated on the label.

Item 7. FRONT LABEL PRECAUTIONARY STATEMENTS - Front panel precautionary statements must be grouped together, preferably within a block outline. The table below shows the minimum type size requirements for various size labels.

Size of Label on Front Panel in Square Inches	Signal Word Minimum Type Size All Capitals	"Keep Out of Reach of Children" Minimum Type Size
5 and under	6 point	6 point
above 5 to 10	10 point	6 point
above 10 to 15	12 point	8 point
above 15 to 30	14 point	10 point
over 30	18 point	12 point

Item 7A. CHILD HAZARD WARNING STATEMENT - The statement "Keep Out of Reach of Children" must be located on the front panel above the signal word except where contact with children during distribution or use is unlikely.
[40 CFR 156.10(h)(1)(ii)]

Item 7B. SIGNAL WORD - The signal word (DANGER, WARNING, or CAUTION) is required on the front panel immediately below the child hazard warning statement.
[40CFR 156.10(h)(1)(i)].

Item 7C. SKULL & CROSSBONES AND WORD "POISON" - On products assigned a toxicity Category I on the basis of oral, dermal, or inhalation toxicity, the word "Poison" shall appear on the label in red on a background of distinctly contrasting color and the skull and crossbones shall appear in immediate proximity to the word POISON.
[40 CFR 156.10(h)(1)(i)].

Item 7D. STATEMENT OF PRACTICAL TREATMENT - A statement of practical treatment (first aid or other) shall appear on the label of pesticide products in toxicity Categories I, II, and III. [40 CFR 156.10(h)(1)(iii)]

Item 7E. REFERRAL STATEMENT - The statement "see Side (or Back) Panel for Additional Precautionary Statements" is required on the front panel for all products, unless all required precautionary statements appear on the front panel. [40 CFR 156.10(h)(1)(iii)].

Item 8. SIDE/BACK PANEL PRECAUTIONARY LABELING - The precautionary statements listed below must appear together on the label under the heading "PRECAUTIONARY STATEMENTS." The preferred location is at the top of the side or back panel preceding the directions for use, and it is preferred that these statements be surrounded by a block outline. Each of the three hazard warning statements must be headed by the appropriate hazard title. [40 CFR 156.10(h)(2)]

Item 8A. HAZARD TO HUMANS AND DOMESTIC ANIMALS - Where a hazard exists to humans or domestic animals, precautionary statements are required indicating the particular hazard, the route(s) of exposure and the precautions to be taken to avoid accident, injury or damage. [40 CFR 156.10(h)(2)(i)]

Item 8B. ENVIRONMENTAL HAZARD - Where a hazard exists to non-target organisms excluding humans and domestic animals, precautionary statements are required stating the nature of the hazard and the appropriate precautions to avoid potential accident, injury, or damage. [40 CFR 156.10(h)(2)(ii)]

Item 8C. PHYSICAL OR CHEMICAL HAZARD - FLAMMABILITY Precautionary statements relating to flammability of a product are required to appear on the label if it meets the criteria in the PHYS/CHEM Labeling Appendix. The requirement is based on the results of the flashpoint determinations and flame extension tests required to be submitted for all products. These statements are to be located in the side/back panel precautionary statements section, preceded by the heading "Physical/Chemical Hazards." Note that no signal word is used in conjunction with the flammability statements.

Item 9A. RESTRICTED USE CLASSIFICATION - FIFRA sec. 3(d) requires that all pesticide formulations/uses be classified for either general or restricted use. Products classified for restricted use may be limited to use by certified applicators or persons under their direct supervision (or may be subject to other restrictions that may be imposed by regulation).

In the Registration Standard, the Agency has (1) indicated certain formulations/uses are to be restricted (Section IV indicates why the product has been classified for restricted use); or (2) reserved any classification decision until appropriate data are submitted.

The Regulatory Position and Rationale states whether products containing this active ingredient are classified for restricted use. If they are restricted the draft label(s) submitted to the Agency as part of your application must reflect this determination (see below).

If you do not believe that your product should be classified for restricted use, you must submit any information and rationale with your application for reregistration. During the Agency's review of your application, your proposed classification determination will be evaluated in accordance with the provisions of 40 CFR 162.11(c). You will be notified of the Agency's classification decision.

Classification Labeling Requirements

If your product has been classified for restricted use, the following label requirements apply:

1. All uses restricted.

   a. The statement "Restricted Use Pesticide" must appear at the top of the front panel of the label. The statement must be set in type of the same minimum size as required for human hazard signal word (see table in 40 CFR 156.10(h)(1)(iv).

   b. Directly below this statement on the front panel, a summary statement of the terms of restriction must appear (including the reasons for restriction if specified in Section I). If use is restricted to certified applicators, the following statement is required: "For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's Certification."

2. Some but not all uses restricted. If the Regulatory Position and Rationale states that some uses are classified for restricted use, and some are unclassified, several courses of action are available:

   a. You may label the product for Restricted use. If you do so, you may include on the label uses that are unrestricted, but you may not distinguish them on the label as being unrestricted.

b. You may delete all restricted uses from your label and submit draft labeling bearing only unrestricted uses.

c. You may "split" your registration, i.e., register two separate products with identical formulations, one bearing only unrestricted uses, and the other bearing restricted uses. To do so, submit two applications for reregistration, each containing all forms and necessary labels. Both applications should be submitted simultaneously. Note that the products will be assigned separate registration numbers.

Item 9B. MISUSE STATEMENT - All products must bear the misuse statement, "It is a violation of Federal law to use this product in a manner inconsistent with its labeling." This statement appears at the beginning of the directions for use, directly beneath the heading of that section.

Item 10A. REENTRY STATEMENT - If a reentry interval has been established by the Agency, it must be included on the label. Additional worker protection statements may be required in accordance with PR Notice 83-2, March 29, 1983.

Item 10B. STORAGE AND DISPOSAL BLOCK - All labels are required to bear storage and disposal statements. These statements are developed for specific containers, sizes, and chemical content. These instructions must be grouped and appear under the heading "Storage and Disposal" in the directions for use. This heading must be set in the same type sizes as required for the child hazard warning. Refer to Appendix II, STOR, PEST/DIS, and CONT/DIS to determine the storage and disposal instructions appropriate for your products.

Item 10C. DIRECTIONS FOR USE - Directions for use must be stated in terms which can be easily read and understood by the average person likely to sue or to supervise the use of the pesticide. When followed, directions must be adequate to protect the public from fraud and from personal injury and to prevent unreasonable adverse effects on the environment. [40 CFR 156.10]

COLLATERAL LABELING

Bulletins, leaflets, circulars, brochures, data sheets, flyers, or other written or graphic printed matter which is referred to on the label or which is to accompany the product are termed collateral labeling. Such labeling may not bear claims or representations that differ in substance from those accepted in connection with registration of the product. It should be made part of the response to this notice and submitted for review.

SUMMARY-7

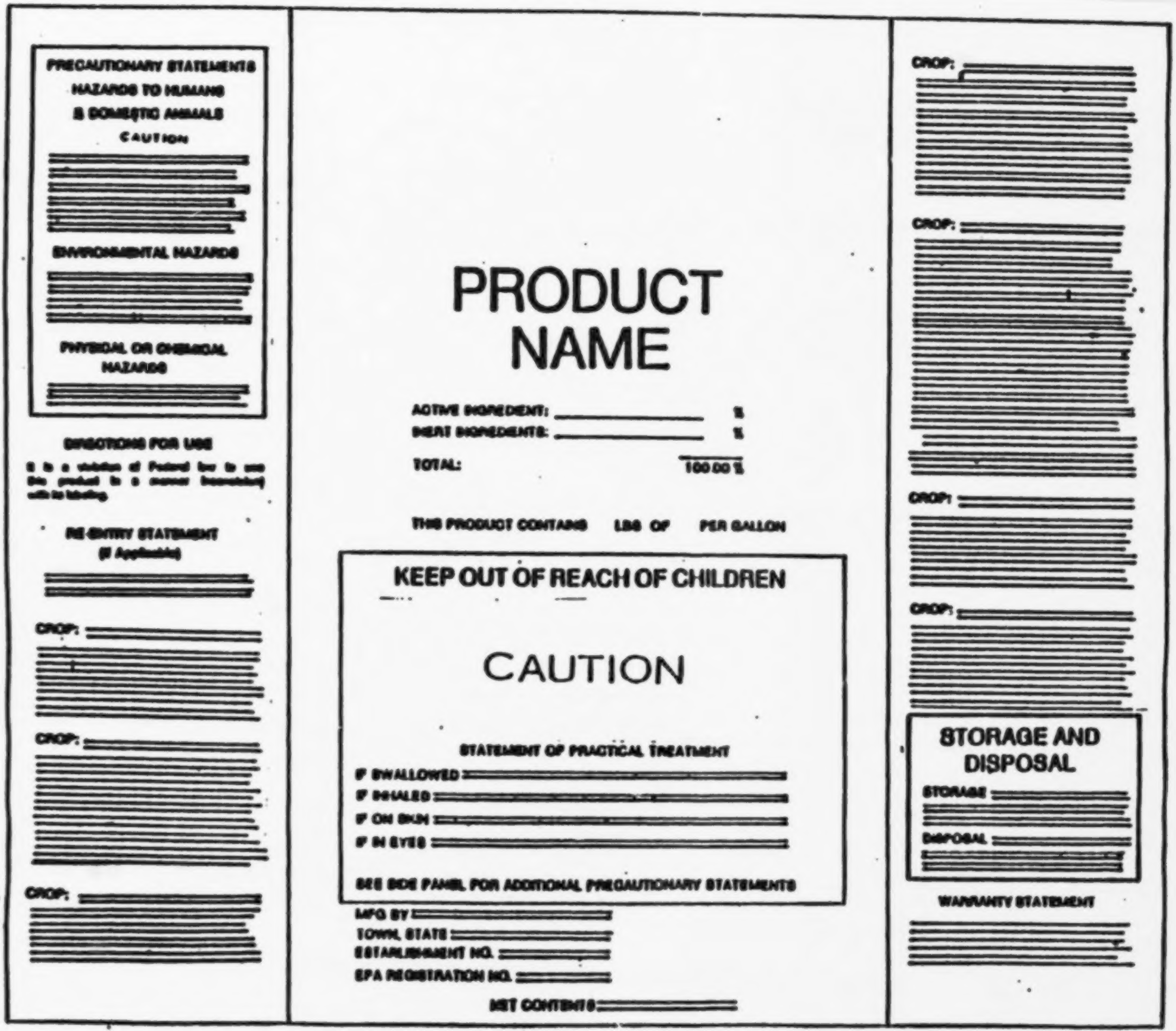
LABELING REQUIREMENTS OF THE FIFRA, AS AMENDED

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
1	Product name	All products	Front panel	Center front panel	
2	Company name and address	All products	None	Bottom front panel or end of label text	If registrant is not the producer, must be qualified by "Packed for . . .," "Distributed by . . . ," etc.
3	Net contents	All products	None	Bottom front panel or end of label text	May be in metric units in addition to U.S. units.
4	EPA Reg. No.	All products	None	Front panel	Must be in similar type size and run parallel to other type.
5	EPA Est. No.	All products	None	Front panel immediately before or following Reg. No.	May appear on the container instead of the label.
6A	Ingredients statement	All products	Front panel	Immediately following product name	Text must run parallel with other text on the panel.
6B	Pounds/gallon statement	Liquid products where dosage is given as lbs. ai/unit area	Front panel	Directly below the main ingredients statement	
7	Front panel precautionary statements	All products	Front panel		All front panel precautionary statements must be grouped together, preferably blocked.
7A	Keep Out of Reach of Children (Child hazard warning)	All products	Front panel	Above signal word	Note type size requirements.
7B	Signal word	All products	Front panel	Immediately below child hazard warning	Note type size requirements.

SUMMARY-8

LABELING REQUIREMENTS OF THE FIFRA, AS AMENDED (cont'd)

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
7C	Skull & crossbones and word POISON (in red)	All products which are Category I based on oral, dermal, or inhalation toxicity	Front panel	Both in close proximity to signal word	
7D	Statement of Practical Treatment or First Aid	All products in Categories I, II, and III	Category I: Front panel unless referral statement is used. Others: Grouped with side panel precautionary statements.	Front panel for all	
7E	Referral statement	All products where precautionary labeling appears on other than front panel	Front panel		
8	Side/back panel precautionary statements	All products	None	Top or side of back panel preceding directions for use	Must be grouped under headings in 8A, 8B, and 8C; preferably blocked.
8A	Hazards to humans and domestic animals	All products in Categories I, II, and III	None	Same as above	Must be preceded by appropriate signal word.
8B	Environmental hazards	All products	None	Same as above	Environmental hazards include bee caution where applicable.



PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS & DOMESTIC ANIMALS

CAUTION

ENVIRONMENTAL HAZARDS

PHYSICAL OR CHEMICAL HAZARDS

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

RE-ENTRY STATEMENT
(If Applicable)

CROP:

CROP:

CROP:

PRODUCT NAME

ACTIVE INGREDIENT: ______ %
INERT INGREDIENTS: ______ %
TOTAL: 100.00 %

THIS PRODUCT CONTAINS LBS OF PER GALLON

KEEP OUT OF REACH OF CHILDREN

CAUTION

STATEMENT OF PRACTICAL TREATMENT

IF SWALLOWED
IF INHALED
IF ON SKIN
IF IN EYES

SEE SIDE PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS

MFG BY
TOWN, STATE
ESTABLISHMENT NO.
EPA REGISTRATION NO.

NET CONTENTS

CROP:

CROP:

CROP:

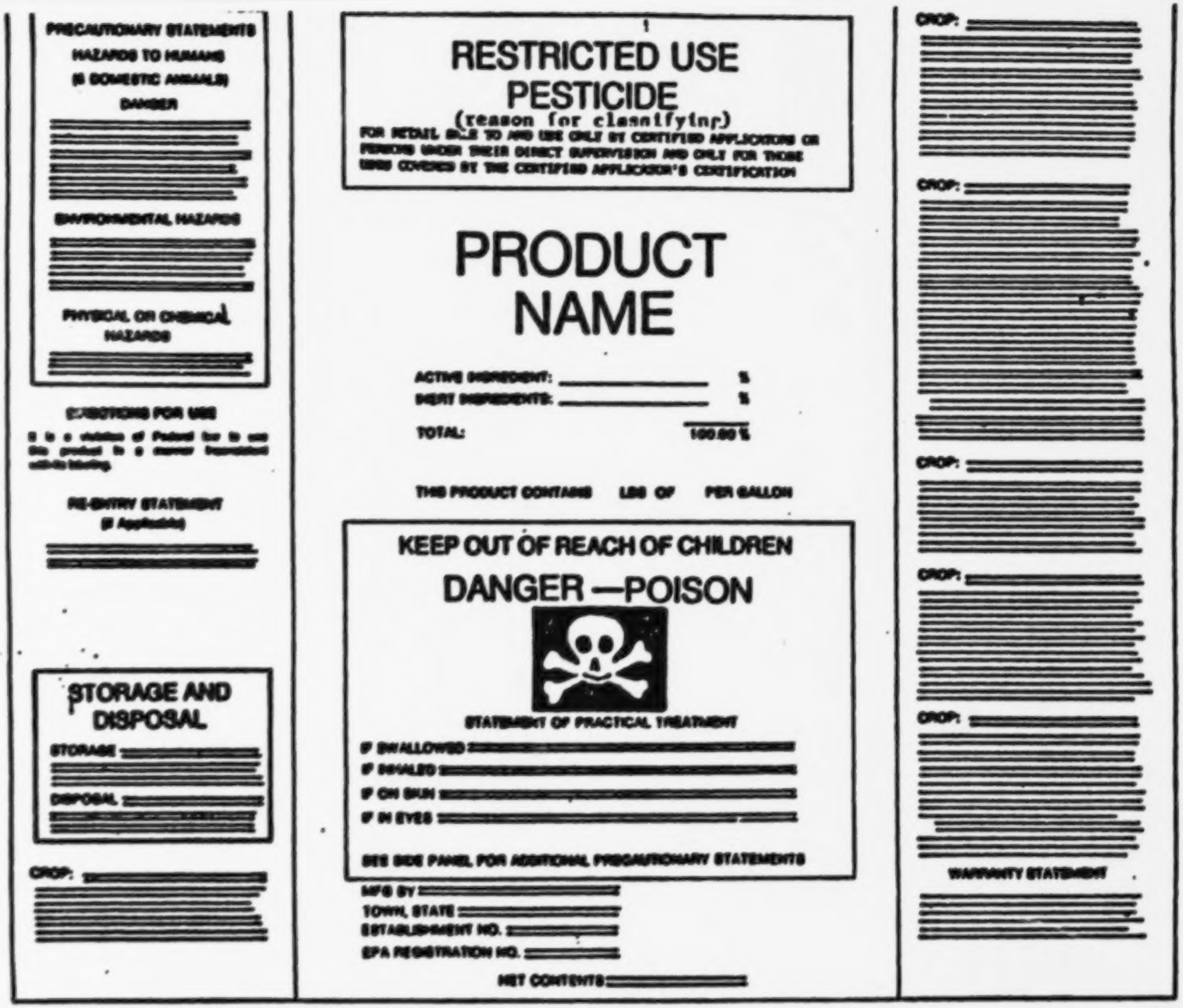
CROP:

STORAGE AND DISPOSAL

STORAGE

DISPOSAL

WARRANTY STATEMENT



PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS

(& DOMESTIC ANIMALS)

DANGER

ENVIRONMENTAL HAZARDS

PHYSICAL OR CHEMICAL HAZARDS

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

RE-ENTRY STATEMENT

(If Applicable)

STORAGE AND DISPOSAL

STORAGE:

DISPOSAL:

CROP:

RESTRICTED USE PESTICIDE

(reason for classifying)

FOR RETAIL SALE TO AND USE ONLY BY CERTIFIED APPLICATORS OR PERSONS UNDER THEIR DIRECT SUPERVISION AND ONLY FOR THOSE USES COVERED BY THE CERTIFIED APPLICATOR'S CERTIFICATION

PRODUCT NAME

ACTIVE INGREDIENT: ______ %

INERT INGREDIENTS: ______ %

TOTAL: 100.00 %

THIS PRODUCT CONTAINS LBS OF PER GALLON

KEEP OUT OF REACH OF CHILDREN

DANGER —POISON

STATEMENT OF PRACTICAL TREATMENT

IF SWALLOWED

IF INHALED

IF ON SKIN

IF IN EYES

SEE SIDE PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS

MFG BY

TOWN, STATE

ESTABLISHMENT NO.

EPA REGISTRATION NO.

NET CONTENTS

CROP:

CROP:

CROP:

CROP:

CROP:

WARRANTY STATEMENT

156

§ [illegible].10 Labeling requirements.

(a) *General*—(1) *Contents of the label.* Every pesticide products shall bear a label containing the information specified by the Act and the regulations in this Part. The contents of a label must show clearly and prominently the following:

(i) The name, brand, or trademark under which the product is sold as prescribed in paragraph (b) of this section;

(ii) The name and address of the producer, registrant, or person for whom produced as prescribed in paragraph (c) of this section;

(iii) The net contents as prescribed in paragraph (d) of this section;

(iv) The product registration number as prescribed in paragraph (e) of this section;

(v) The producing establishment number as prescribed in paragraph (f) of this section;

(vi) An ingredient statement as prescribed in paragraph (g) of this section;

(vii) Warning or precautionary statements as prescribed in paragraph (h) of this section;

(viii) The directions for use as prescribed in paragraph (i) of this section; and

(ix) The use classification(s) as prescribed in paragraph (j) of this section.

(2) *Prominence and legibility.* (i) All words, statements, graphic representations, designs or other information required on the labeling by the Act or the regulations in this part must be clearly legible to a person with normal vision, and must be placed with such conspicuousness (as compared with other words, statements, designs, or graphic matter on the labeling) and expressed in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

(ii) All required label text must:

(A) Be set in 6-point or larger type;

(B) Appear on a clear contrasting background; and

(C) Not be obscured or crowded.

(3) *Language to be used.* All required label or labeling text shall appear in the English language. However, the Agency may require or the applicant may propose additional text in other languages as is considered necessary to protect the public. When additional text in another language is necessary, all labeling requirements will be applied equally to both the English and other-language versions of the labeling.

(4) *Placement of Label*—(i) *General.* The label shall appear on or be securely attached to the immediate container of the pesticide product. For purposes of this Section, and the misbranding provisions of the Act, "securely attached" shall mean that a label can reasonably be expected to remain affixed during the foreseeable conditions and period of use. If the immediate container is enclosed within a wrapper or outside container through which the label cannot be clearly read, the label must also be securely attached to such outside wrapper or container, if it is a part of the package as customarily distributed or sold.

(ii) *Tank cars and other bulk containers*—(A) *Transportation.* While a pesticide product is in transit, the appropriate provisions of 49 CFR Parts 170-189, concerning the transportation of hazardous materials, and specifically those provisions concerning the labeling, marking and placarding of hazardous materials and the vehicles carrying them, define the basic Federal requirements. In addition, when any registered pesticide product is transported in a tank car, tank truck or other mobile or portable bulk container, a copy of the accepted label must be attached to the shipping papers, and left with the consignee at the time of delivery.

(B) *Storage.* When pesticide products are stored in bulk containers, whether mobile or stationary, which remain in the custody of the user, a copy of the label of labeling, including all appropriate directions for use, shall be securely attached to the container in the immediate vicinity of the discharge control valve.

(5) *False or misleading statements.* Pursuant to section 2(q)(1)(A) of the Act, a pesticide or a device declared subject to the Act pursuant to § 162.15, is misbranded if its labeling is false or misleading in any particular including both pesticidal and non-pesticidal claims. Examples of statements or representations in the labeling which constitute misbranding include:

(i) A false or misleading statement concerning the composition of the product;

(ii) A false or misleading statement concerning the effectiveness of the product as a pesticide or device;

(iii) A false or misleading statement about the value of the product for purposes other than as a pesticide or device;

(iv) A false or misleading comparison with other pesticides or devices;

(v) Any statement directly or indirectly implying that the pesticide or device is recommended or endorsed by any agency of the Federal Government;

(vi) The name of a pesticide which contains two or more principal active ingredients if the name suggests one or more but not all such principal active ingredients even though the names of the other ingredients are stated elsewhere in the labeling;

(vii) A true statement used in such a way as to give a false or misleading impression to the purchaser;

(viii) Label disclaimers which negate or detract from labeling statements required under the Act and these regulations;

(ix) Claims as to the safety of the pesticide or its ingredients, including statements such as "safe," "nonpoisonous," "noninjurious," "harmless" or "nontoxic to humans and pets" with or without such a qualifying phrase as "when used as directed"; and

(x) Non-numerical and/or comparative statements on the safety of the product, including but not limited to:

(A) "Contains all natural ingredients";

(B) "Among the least toxic chemicals known"

(C) "Pollution approved"

(6) *Final printed labeling.* (i) Except as provided in paragraph (a)(6)(ii) of this section, final printed labeling must be submitted and accepted prior to registration. However, final printed labeling need not be submitted until draft label texts have been provisionally accepted by the Agency.

(ii) Clearly legible reproductions or photo reductions will be accepted for unusual labels such as those silk-screened directly onto glass or metal containers or large bag or drum labels. Such reproductions must be of microfilm reproduction quality.

(b) *Name, brand, or trademark.* (1) The name, brand, or trademark under which the pesticide product is sold shall appear on the front panel of the label.

(2) No name, brand, or trademark may appear on the label which:

(i) Is false or misleading, or

(ii) Has not been approved by the Administrator through registration or supplemental registration as an additional name pursuant to § 162.6(b)(4).

(c) Name and address of producer, registrant, or person for whom produced. An unqualified name and address given on the label shall be considered as the name and address of the producer. If the registrant's name appears on the label and the registrant is not the producer, or if the name of the person for whom the pesticide was produced appears on the label, it must be qualified by appropriate wording such as "Packed for * * *," "Distributed by * * *," or "Sold by * * *" to show that the name is not that of the producer.

(d) *Net weight or measure of contents.* (1) The net weight or measure of content shall be exclusive of wrappers or other materials and shall be the average content unless explicitly stated as a minimum quantity.

(2) If the pesticide is a liquid, the net content statement shall be in terms of liquid measure at 68° F (20°C) and shall be expressed in conventional American units of fluid ounces, pints, quarts, and gallons.

(3) If the pesticide is solid or semisolid, viscous or pressurized, or is a mixture of liquid and solid, the net content statement shall be in terms of weight expressed as avoirdupois pounds and ounces.

(4) In all cases, net content shall be stated in terms of the largest suitable units, i.e., "1 pound 10 ounces" rather than "26 ounces."

(5) In addition to the required units specified, net content may be expressed in metric units.

(6) Variation above minimum content or around an average is permissible only to the extent that it represents deviation unavoidable in good manufacturing practice. Variation below a stated minimum is not permitted. In no case shall the average content of the packages in a shipment fall below the stated average content.

(e) *Product registration number.* The registration number assigned to the pesticide product at the time of registration shall appear on the label, preceded by the phrase "EPA Registration No.," or the phrase "EPA Reg. No." The registration number shall be set in type of a size and style similar to other print on that part of the label on which it appears and shall run parallel to it. The registration number and the required identifying phrase shall not appear in such a manner as to suggest or imply recommendation or endorsement of the product by the Agency.

(f) *Producing establishments registration number.* The producing establishment registration number preceded by the phrase "EPA Est.", of the final establishment at which the product was produced may appear in any suitable location on the label or immediate container. It must appear on the wrapper or outside container of the package if the EPA establishment registration number on the immediate container cannot be clearly read through such wrapper or container.

(g) *Ingredient statement*—(1) *General.* The label of each pesticide product must bear a statement which contains the name and percentage by weight of each active ingredient, the total percentage by weight of all inert ingredients; and if the pesticide contains arsenic in any form, a statement of the percentages of total and water-soluble arsenic calculated as elemental arsenic. The active ingredients must be designated by the term "active ingredients" and the inert ingredients by the term "inert ingredients," or the singular forms of these terms when appropriate. Both terms shall be in the same type size, be aligned to the same margin and be equally prominent. The statement "Inert Ingredients, none" is not required for pesticides which contain 100 percent active ingredients. Unless the ingredient statement is a complete analysis of the pesticide, the term "analysis" shall not be used as a heading for the ingredient statement.

(2) *Position of ingredient statement.* (i) The ingredient statement is normally required on the front panel of the label. If there is an outside container or wrapper through which the ingredient statement cannot be clearly read, the ingredient statement must also appear on such outside container or wrapper. If the size or form of the package makes it impracticable to place the ingredient statement on the front panel of the label, permission may be granted for the ingredient statement to appear elsewhere.

(ii) The text of the ingredient statement must run parallel with other text on the panel on which it appears, and must be clearly distinguishable from and must not be placed in the body of other text.

(3) *Names to be used in ingredient statement.* The name used for each ingredient shall be the accepted common name, if there is one, followed by the chemical name. The common name may be used alone only if it is well known. If no common name has been established, the chemical name alone shall be used. In no case will the use of a trademark or proprietary name be permitted unless such name has been accepted as a common name by the Administrator under the authority of section 25(c)(6).

(4) *Statements of percentages.* The percentages of ingredients shall be stated in terms of weight-to-weight. The sum of percentages of the active and the inert ingredients shall be 100. Percentages shall not be expressed by a range of values such as "22-25%." If the uses of the pesticide product are expressed as weight of active ingredient per unit area, a statement of the weight of active ingredient per unit volume of the pesticide formulation shall also appear in the ingredient statement.

(5) *Accuracy of stated percentages.* The percentages given shall be as precise as possible reflecting good manufacturing practice. If there may be unavoidable variation between manufacturing batches, the value stated for each active ingredient shall be the lowest percentage which may be present.

(6) *Deterioration.* Pesticides which change in chemical composition significantly must meet the following labeling requirements:

(i) In cases where it is determined that a pesticide formulation changes chemical composition significantly, the product must bear the following statement in a prominent position on the label: "Not for sale or use after [date]."

(ii) The product must meet all label claims up to the expiration time indicated on the label.

(7) *Inert ingredients.* The Administrator may require the name of any inert ingredient(s) to be listed in the ingredient statement if he determines that such ingredient(s) may pose a hazard to man or the environment.

(h) *Warnings and precautionary statements.* Required warnings and precautionary statements concerning the general areas of toxicological hazard including hazard to children, environmental hazard, and physical or chemical hazard fall into two groups; those required on the front panel of the labeling and those which may appear elsewhere. Specific requirements concerning content, placement, type size, and prominence are given below.

(1) *Required front panel statements.* With the exception of the child hazard warning statement, the text required on the front panel of the label is determined by the Toxicity Category of the pesticide. The category is assigned on the basis of the highest hazard shown by any of the indicators in the table below:

Hazard indicators	Toxicity categories			
	I	II	III	IV
Oral LD_{50}	Up to and including 50 mg/kg.	From 50 thru 500 mg/kg.	From 500 thru 5000 mg/kg.	Greater than 5000 mg/kg.
Inhalation LC_{50}	Up to and including .2 mg/liter.	From .2 thru 2 mg/liter.	From 2. thru 20 mg/liter.	Greater than 20 mg/liter.
Dermal LD_{50}	Up to and including 200 mg/kg.	From 200 thru 2000	From 2,000 thru 20,000	Greater than 20,000
Eye effects	Corrosive; corneal opacity not reversible within 7 days.	Corneal opacity reversible within 7 days; irritation persisting for 7 days.	No corneal opacity; irritation reversible within 7 days.	No irritation.
Skin effects	Corrosive	Severe irritation at 72 hours.	Moderate irritation at 72 hours.	Mild or slight irritation at 72 hours.

(i) *Human hazard signal word*—(A) *Toxicity Category I.* All pesticide products meeting the criteria of Toxicity Category I shall bear on the front panel the signal word "Danger." In addition if the product was assigned to Toxicity Category I on the basis of its oral, inhalation or dermal toxicity (as distinct from skin and eye local effects) the word "Poison" shall appear in red on a background of distinctly contrasting color and the skull and crossbones shall appear in immediate proximity to the word "poison."

(B) *Toxicity Category II.* All pesticide products meeting the criteria of Toxicity Category II shall bear on the front panel the signal word "Warning."

(C) *Toxicity Category III.* All pesticide products meeting the criteria of Toxicity Category III shall bear on the front panel the signal word "Caution."

(D) *Toxicity Category IV.* All pesticide products meeting the criteria of Toxicity Category IV shall bear on the front panel the signal word "Caution."

(E) *Use of signal words.* Use of any signal word(s) associated with a higher Toxicity Category is not permitted except when the Agency determines that such labeling is necessary to prevent unreasonable adverse effects on man or the environment. In no case shall more than one human hazard signal word appear on the front panel of a label.

(ii) *Child hazard warning.* Every pesticide product label shall bear on the front panel the statement "keep out of reach of children." Only in cases where the likelihood of contact with children during distribution, marketing, storage or use is demonstrated by the applicant to be extremely remote, or if the nature of the pesticide is such that it is approved for use on infants or small children, may the Administrator waive this requirement.

(iii) *Statement of practical treatment*—(A) *Toxicity Category I.* A statement of practical treatment (first aid or other) shall appear on the front panel of the label of all pesticides falling into Toxicity Category I on the basis of oral, inhalation or dermal toxicity. The Agency may, however, permit reasonable variations in the placement of the statement of practical treatment is some reference such as "See statement of practical treatment on back panel" appears on the front panel near the word "Poison" and the skull and crossbones.

(B) *Other toxicity categories.* The statement of practical treatment is not required on the front panel except as described in paragraph (h)(1)(iii)(A) of this section. The applicant may, however, include such a front panel statement at his option. Statements of practical treatment are, however, required elsewhere on the label in accord with paragraph (h)(2) of this section if they do not appear on the front panel.

(iv) *Placement and prominence.* All the require front panel warning statements shall be grouped together on the label, and shall appear with sufficient prominence relative to other front panel text and graphic material to make them unlikely to be overlooked under customary conditions of purchase and use. The following table shows the minimum type size requirements for the front panel warning statements on various sizes of labels:

Size of label front panel in square inches	Points	
	Required signal word, all capitals	"Keep out of reach of children"
5 and under	6	6
Above 5 to 10	10	6
Above 10 to 15	12	8
Above 15 to 30	14	10
Over 30	18	12

(2) *Other required warnings and precautionary statements.* The warnings and precautionary statements as required below shall appear together on the label under the general heading "Precautionary Statements" and under appropriate subheadings of "Hazard to Humans and Domestic Animals," "Environmental Hazard" and "Physical or Chemical Hazard."

(i) *Hazard to humans and domestic animals.* (A) Where a hazard exists to humans or domestic animals, precautionary statements are required indicating the particular hazard, the route(s) of exposure and the precautions to be taken to avoid accident, injury or damage. The precautionary paragraph shall be immediately preceded by the appropriate hazard signal word.

(B) The following table depicts typical precautionary statements. These statements must be modified or expanded to reflect specific hazards.

Toxicity category	Precautionary statements by toxicity category	
	Oral, inhalation, or dermal toxicity	Skin and eye local effects
I	Fatal (poisonous) if swallowed [inhaled or absorbed through skin]. Do not breathe vapor [dust or spray mist]. Do not get in eyes, on skin, or on clothing [Front panel statement of practical treatment required.].	Corrosive, causes eye and skin damage [or skin irritation]. Do not get in eyes, on skin, or on clothing. Wear goggles or face shield and rubber gloves when handling. Harmful or fatal if swallowed. [Appropriate first aid statement required.]
II	May be fatal if swallowed [inhaled or absorbed through the skin]. Do not breathe vapors [dust or spray mist]. Do not get in eyes, on skin, or on clothing. [Appropriate first aid statements required.].	Causes eye [and skin] irritation. Do not get in eyes, on skin, or on clothing. Harmful if swallowed. [Appropriate first aid statement required.]
III	Harmful if swallowed [inhaled or absorbed through the skin]. Avoid breathing vapors [dust or spray mist]. Avoid contact with skin [eyes or clothing]. [Appropriate first aid statement required.].	Avoid contact with skin, eyes or clothing. In case of contact immediately flush eyes or skin with plenty of water. Get medical attention if irritation persists.
IV	[No precautionary statements required.]	[No precautionary statements required.]

(ii) *Environmental hazards.* Where a hazard exists to non target organisms excluding humans and domestic animals, precautionary statements are required stating the nature of the hazard and the appropriate precautions to avoid potential accident, injury or damage. Examples of the

(C) Warnings as required against use on certain crops, animals, objects, or in or adjacent to certain areas.

(D) [Reserved]

(E) For restricted use pesticides, a statement that the pesticide may be applied under the direct supervision of a certified applicator who is not physically present at the site of application but nonetheless available to the person applying the pesticide, unless the Agency has determined that the pesticide may only be applied under the direct supervision of a certified applicator who is physically present.

(F) Other pertinent information which the Administrator determines to be necessary for the protection of man and the environment.

(j) *Statement of Use Classification.* By October 22, 1976, all pesticide products must bear on their labels a statement of use classification as described in paragraphs (j) (1) and (2) of this section. Any pesticide product for which some uses are classified for general use and others for restricted use shall be separately labeled according to the labeling standards set forth in this subsection, and shall be marketed as separate products with different registration numbers, one bearing directions only for general use(s) and the other bearing directions for restricted use(s) except that, if a product has both restricted use(s) and general use(s), both of these uses may appear on a product labeled for restricted use. Such products shall be subject to the provisions of § 162.10(j)(2).

(1) *General Use Classification.* Pesticide products bearing directions for use(s) classified general shall be labeled with the exact words "General Classification" immediately below the heading "Directions for Use." And reference to the general classification that suggests or implies that the general utility of the pesticide extends beyond those purposes and uses contained in the Directions for Use will be considered a false or misleading statement under the statutory definitions of misbranding.

(2) *Restricted Use Classification.* Pesticide products bearing direction for use(s) classified restricted shall bear statements of restricted use classification on the front panel as described below:

(i) *Front panel statement of restricted use classification.* (A) At the top of the front panel of the label, set in type of the same minimum sizes as required for human hazard signal words (see table in § 162.10(h)(1)(iv)), and appearing with sufficient prominence relative to other text and graphic material on the front panel to make it unlikely to be overlooked under customary conditions of purchase and use, the statement "Restricted Use Pesticide" shall appear.

(B) Directly below this statement on the front panel, a summary statement of the terms of restriction imposed as a precondition to registration shall appear. If use is restricted to certified applicators, the following statement is required: "For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's certification." If, however, other regulatory restrictions are imposed, the Administrator will define the appropriate wording for the terms of restriction by regulation.

(k) Advertising. [Reserved]

[40 FR 28268, July 3, 1975; 40 FR 32329, Aug. 1, 1975; 40 FR 36571, Aug. 21, 1975, as amended at 43 FR 5786, Feb. 9, 1978] tions for use may be omitted from labeling of pesticides which are intended for use only by manufacturers of products other than pesticide products in their regular manufacturing processes, provided that:

(*1*) The label clearly shows that the product is intended for use only in manufacturing processes and specifies the type(s) of products involved.

(*2*) Adequate information such as technical data sheets or bulletins, is available to the trade specifying the type of product involved and its proper use in manufacturing processes;

(*3*) The product will not come into the hands of the general public except after incorporation into finished products; and

(*4*) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment.

(B) Detailed directions for use may be omitted from the labeling of pesticide products for which sale is limited to physicians, veterinarians, or druggists, provided that:

(*1*) The label clearly states that the product is for use only by physicians or veterinarians;

(*2*) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment; and

(*3*) The product is also a drug and regulated under the provisions of the Federal Food, Drug and Cosmetic Act.

(C) Detailed directions for use may be omitted from the labeling of pesticide products which are intended for use only by formulators in preparing pesticides for sale to the public, provided that:

(*1*) There is information readily available to the formulators on the composition, toxicity, methods of use, applicable restrictions or limitations, and effectiveness of the product for pesticide purposes;

(*2*) The label clearly states that the product is intended for use only in manufacturing, formulating, mixing, or repacking for use as a pesticide and specifies the type(s) of pesticide products involved;

(*3*) The product as finally manufactured, formulated, mixed, or repackaged is registered; and

(*4*) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment.

(2) *Contents of Directions for Use.* The directions for use shall include the following, under the headings "Directions for Use":

(i) The statement of use classification as prescribed in 162.10(j) immediately under the heading "Directions for Use."

(ii) Immediately below the statement of use classification, the statement "It is a violation of Federal law to use this product in a manner inconsistent with its labeling."

(iii) The site(s) of application, as for example the crops, animals, areas, or objects to be treated.

(iv) The target pest(s) associated with each site.

(v) The dosage rate associated with each site and pest.

(vi) The method of application, including instructions for dilution, if required, and type(s) of application apparatus or equipment required.

(vii) The frequency and timing of applications necessary to obtain effective results without causing unreasonable adverse effects on the environment.

(viii) Specific limitations on reentry to areas where the pesticide has been applied, meeting the requirements concerning reentry provided by 40 CFR Part 170.

(ix) Specific directions concerning the storage and disposal of the pesticide and its container, meeting the requirements of 40 CFR Part 165. These instructions shall be grouped and appear under the heading "Storage and Disposal." This heading must be set in type of the same minimum sizes as required for the child hazard warning. (See Table in § 162.10(h)(1)(iv))

(x) Any limitations or restrictions on use required to prevent unreasonable adverse effects, such as:

(A) Required intervals between application and harvest of food or feed crops.

(B) Rotational crop restrictions.

hazard statements and the circumstances under which they are required follow:

(A) If a pesticide intended for outdoor use contains an active ingredient with a mammalian acute oral LD_{50} of 100 or less, the statement "This Pesticide is Toxic to Wildlife" is required.

(B) If a pesticide intended for outdoor use contains an active ingredient with a fish acute LC_{50} of 1 ppm or less, the statement "This Pesticide is Toxic to Fish" is required.

(C) If a pesticide intended for outdoor use contains an active ingredient with an avian acute oral LD_{50} of 100 mg/kg or less, or a subacute dietary LC_{50} of 500 ppm or less, the statement "This Pesticide is Toxic to Wildlife" is required.

(D) If either accident history or field studies demonstrate that use of the pesticide may result in fatality to birds, fish or mammals, the statement "This pesticide is extremely toxic to wildlife (fish)" is required.

(E) For uses involving foliar application to agricultural crops, forests, or shade trees, or for mosquito abatement treatments, pesticides toxic to pollinating insects must bear appropriate label cautions.

(F) For all outdoor uses other than aquatic applications the label must bear the caution "Keep out of lakes, ponds or streams. Do not contaminate water by cleaning of equipment or disposal of wastes."

(iii) *Physical or chemical hazards.* Warning statements on the flammability or explosive characteristics of the pesticide are required as follows:

Flash point	Required text
(A) PRESSURIZED CONTAINERS	
Flash point at or below 20° F; if there is a flashback at any valve opening.	Extremely flammable. Contents under pressure. Keep away from fire, sparks, and heated surfaces. Do not puncture or incinerate container. Exposure to temperatures above 130° F may cause bursting.
Flash point above 20° F and not over 80° F or if the flame extension is more than 18 in long at a distance of 6 in from the flame.	Flammable. Contents under pressure. Keep away from heat, sparks, and open flame. Do not puncture or incinerate container. Exposure to temperatures above 130° F may cause bursting.
All other pressurized containers	Contents under pressure. Do not use or store near heat or open flame. Do not puncture or incinerate container. Exposure to temperatures above 130° F may cause bursting.
(B) NONPRESSURIZED CONTAINERS	
At or below 20° F	Extremely flammable. Keep away from fire, sparks, and heated surfaces.
Above 20° F and not over 80° F	Flammable. Keep away from heat and open flame.
Above 80° F and not over 150° F	Do not use or store near heat or open flame.

(i) *Directions for Use*—(1) *General requirements*—(i) *Adequacy and clarity of directions.* Directions for use must be stated in terms which can be easily read and understood by the average person likely to use or to supervise the use of the pesticide. When followed, directions must be adequate to protect the public from fraud and from personal injury and to prevent unreasonable adverse effects on the environment.

(ii) *Placement of directions for use.* Directions may appear on any portion of the label provided that they are conspicuous enough to be easily read by the user of the pesticide product. Directions for use may appear on printed or graphic matter which accompanies the pesticide provided that:

(A) If required by the Agency, such printed or graphic matter is securely attached to each package of the pesticide, or placed within the outside wrapper or bag;

(B) The label bears a reference to the directions for use in accompanying leaflets or circulars, such as "See directions in the enclosed circular:" and

(C) The Administrator determines that it is not necessary for such directions to appear on the label.

(iii) *Exceptions to requirement for direction for use*—(A) Detailed direc-

PHYSICAL-CHEMICAL HAZARDS

Criteria	Required Label Statement
I. Pressurized Containers	
A. Flashpoint at or below 20°F; or if there is a flashback at any valve opening.	Extremely flammable. Contents under pressure. Keep away from fire, sparks, and heated surfaces. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
B. Flashpoint above 20°F and not over 80°F; or if the flame extension is more than 18 inches long at a distance of 6 inches from the valve opening.	Flammable. Contents under pressure. Keep away from heat, sparks, and flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
C. ALL OTHER PRESSURIZED CONTAINERS	Contents under pressure. Do not use or store near heat or open flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
II. Non-Pressurized Containers	
A. Flashpoint at or below 20°F.	Extremely flammable. Keep away from fire, sparks, and heated surfaces.
B. Flashpoint above 20°F and not over 80°F.	Flammable. keep away from heat and open flame.
C. Flashpoint over 80°F and not over 150°F.	Do not use or store near heat and open flame.
D. Flashpoint above 150°F.	None required.

STORAGE INSTRUCTIONS FOR PESTICIDES

Heading:

All products are required to bear specific label instructions about storage and disposal. Storage and disposal instructions must be grouped together in the directions for use portion of the label under the heading STORAGE AND DISPOSAL. Products intended solely for domestic use need not include the heading "STORAGE AND DISPOSAL."

Storage Instructions:

All product labels are required to have appropriate storage instructions. Specific storage instructions are not prescribed. Each registrant must develop his own storage instructions, considering, when applicable, the following factors:

1. Conditions of storage that might alter the composition or usefulness of the pesticide. Examples could be temperature extremes, excessive moisture or humidity, heat, sunlight, friction, or contaminating substances or media.

2. Physical requirements of storage which might adversely affect the container of the product and its ability to continue to function properly. Requirements might include positioning of the container in storage, storage or damage due to stacking, penetration of moisture, and ability to withstand shock or friction.

3. Specifications for handling the pesticide container, including movement of container within the storage area, proper opening and closing procedures (particularly for opened containers), and measures to minimize exposure while opening or closing container.

4. Instructions on what to do if the container is damaged in any way, or if the pesticide is leaking or has been spilled, and precautions to minimize exposure if damage occurs.

5. General precautions concerning locked storage, storage in original container only, and separation of pesticides during storage to prevent cross-contamination of other pesticides, fertilizer, food, and feed.

6. General storage instructions for household products should emphasize storage in original container and placement in locked storage areas.

PESTICIDE DISPOSAL INSTRUCTIONS

The label of all products, except those intended solely for domestic use, must bear explicit instructions about pesticide disposal. The statements listed below contain the exact wording that must appear on the label of these products:

1. The labels of all products, except domestic use, must contain the statement, "Do not contaminate water, food, or feed by storage or disposal."

2. Except those products intended solely for domestic use, the labels of all products that contain active ingredients that are Acute Hazardous Wastes or are assigned to Toxicity Category I on the basis of oral or dermal toxicity, or Toxicity Category I or II on the basis of acute inhalation toxicity must bear the following pesticide disposal statement:

> "Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency or the Hazardous Waste representative at the nearest EPA Regional Office for guidance."

3. The labels of all products, except those intended for domestic use, containing active or inert ingredients that are Toxic Hazardous Wastes or meet any of the criteria in 40 CFR 261, Subpart C for a hazardous waste must bear the following pesticide disposal statement:

> "Pesticide wastes are toxic. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance."

4. Labels for all other products, except those intended for domestic use, must bear the following pesticide disposal statement:

> "Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility."

5. Products intended for domestic use only must bear the following disposal statement: "Securely wrap original container in several layers of newspaper and discard in trash."

CONT/DIS-1

CONTAINER DISPOSAL INSTRUCTIONS

The label of each product must bear container disposal instructions appropriate to the type of container.

1. Domestic use products must bear one of the following container disposal statements:

Container Type	Statement
Non-aerosol products (bottles, cans, jars)	Do not reuse container (bottle, can, jar). Rinse thoroughly before discarding in trash.
Non-aerosol products (bags)	Do not reuse bag. Discard bag in trash.
Aerosol products	Replace cap and discard containers in trash. Do not incinerate or puncture.

2. All other products must bear container disposal instructions, based on container type, listed below:

Container Type	Statement
Metal containers (non-aerosol)	Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.
Plastic containers	Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.
Glass containers	Triple rinse (or equivalent). Then dispose of in a sanitary landfill or by other approved state and local procedures.
Fiber drums with liners	Completely empty liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into application equipment. Then dispose of liner in a sanitary landfill or by incineration if allowed by state and local authorities. If drum is contaminated and cannot be reused[1], dispose of in the same manner.
Paper and plastic bags	Completely empty bag into application equipment. Then dispose of empty bag in a sanitary landfill or by incineration, or, if allowed by State and local authorities, by burning. If burned, stay out of smoke.
Compressed gas cylinders	Return empty cylinder for reuse (or similar wording).

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[1] Manufacturer may replace this phrase with one indicating whether and how fiber drum may be reused.

IV. BIBLIOGRAPHY APPENDICES

Guide to Use of This Bibliography

1. CONTENT OF BIBLIOGRAPHY. This bibliography contains citations of all studies considered relevant by EPA in arriving at the positions and conclusions stated elsewhere in the Standard. Primary sources for studies in this bibliography have been the body of data submitted to EPA and its predecessor agencies in support of past regulatory decisions. Selections from other sources including the published literature, in those instances where they have been considered, will be included.

2. UNITS OF ENTRY. The unit of entry in this bibliography is called a "study." In the case of published materials, this corresponds closely to an article. In the case of unpublished materials submitted to the Agency, the Agency has sought to identify documents at a level parallel to the published article from within the typically larger volumes in which they were submitted. The resulting "studies" generally have a distinct title (or at least a single subject), can stand alone for purposes of review, and can be described with a conventional bibliographic citation. The Agency has attempted also to unite basic documents and commentaries upon them, treating them as a single study.

3. IDENTIFICATION OF ENTRIES. The entries in this bibliography are sorted numerically by "Master Record Identifier," or MRID, number. This number is unique to the citation, and should be used at any time specific reference is required. It is not related to the six-digit "Accession Number" which has been used to identify volumes of submitted studies; see paragraph 4(d)(4) below for a further explanation. In a few cases, entries added to the bibliography late in the review may be preceded by a nine-character temporary identifier. These entries are listed after all MRID entries. This temporary identifier number is also to be used whenever specific reference is needed.

4. FORM OF ENTRY. In addition to the Master Record Identifier (MRID), each entry consists of a citation containing standard elements followed, in the case of material submitted to EPA, by a description of the earliest known submission. Bibliographic conventions used reflect the standards of the American National Standards Institute (ANSI), expanded to provide for certain special needs.

    a. Author. Whenever the Agency could confidently identify one, the Agency has chosen to show a personal author. When no individual was identified, the Agency has shown an identifiable laboratory or testing facility as author. As a last resort, the Agency has shown the first submitter as author.

b. Document Date. When the date appears as four digits with no question marks, the Agency took it directly from the document. When a four-digit date is followed by a question mark, the bibliographer deduced the date from evidence in the document. When the date appears as (19??), the Agency was unable to determine or estimate the date of the document.

c. Title. In some cases, it has been necessary for Agency bibliographers to create or enhance a document title. Any such editorial insertions are contained between square brackets.

d. Trailing Parentheses. For studies submitted to the Agency in the past, the trailing parentheses include (in addition to any self-explanatory text) the following elements describing the earliest known submission:

   (1) Submission Date. The date of the earliest known submission appears immediately following the word "received."

   (2) Administrative Number. The next element, immediately following the word "under," is the registration number, experimental use permit number, petition number or other administrative number associated with the earliest known submission.

   (3) Submitter. The third element is the submitter, following the phrase "submitted by." When authorship is defaulted to the submitter, this element is omitted.

   (4) Volume Identification (Accession Numbers). The final element in the trailing parentheses identifies the EPA accession number of the volume in which the original submission of the study appears. The six-digit accession number follows the symbol "CDL," standing for "Company Data Library." This accession number is in turn followed by an alphabetic suffix which shows the relative position of the study within the volume. For example, within accession number 123456, the first study would be 123456-A; the second, 123456-B; the 26th, 123456-Z; and the 27th, 123456-AA.

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IV. FORMS APPENDICES

EPA Form 8580-1

OMB Approval No. 2070-0057
Expires 11/30/89

FIFRA SECTION 3(C)(2)(B) SUMMARY SHEET

EPA REGISTRATION NO

PRODUCT NAME

APPLICANT'S NAME

DATE GUIDANCE DOCUMENT ISSUED

With respect to the requirement to submit "generic" data imposed by the FIFRA section 3(C)(2)(B) notice contained in the referenced Guidance Document, I am responding in the following manner:

☐ 1. I will submit data in a timely manner to satisfy the following requirements. If the test procedures I will use deviate from (or are not specified in) the Registration Guidelines or the Protocols contained in the Reports of Expert Groups to the Chemicals Group, OECD Chemicals Testing Programme, I enclose the protocols that I will use:

Attach separate page with a list of the data requirements your company agrees to satisfy.

☐ 2. I have entered into an agreement with one or more other registrants under FIFRA section 3(C)(2)(B)(ii) to satisfy the following data requirements. The tests, and any required protocols, will be submitted to EPA by:

NAME OF OTHER REGISTRANT

Attach list of data requirements

☐ 3. I enclose a completed "Certification of Attempt to Enter Into an Agreement with Other Registrants for Development of Data" with respect to the following data requirements.

☐ 4. I request that you amend my registration by deleting the following uses (this option is not available to applicants for new products):

☐ 5. I request voluntary cancellation of the registration of this product. (This option is not available to applicants for new products.)

REGISTRANT'S AUTHORIZED REPRESENTATIVE	SIGNATURE	DATE